Contested framings and policy evolution:

Evolution of the GM biosafety policy-making process in Iran, 2006-2009

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Dphil in Science, Technology and Innovation Policy Studies

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Submitted November 2010

Declaration

I hereby declare that this thesis has not been and will not be, submitted in whole or in part to another University for the award of any other degree.

To my wife and my two sons

Acknowledgements

This study could not have been finished without the helps and inputs of several people and organisations. I hope to name at least the several people and organisations who had a major role in accomplishment of this study.

First of all, I should express my greatest thanks to two different groups who have been supporting me during the research. The first one is my family, including my wife and two children. In parallel, I should name my supervisor, Prof. Erik Millstone and then Dr. Patrick Van Zwanenberg whose role in advising the current research and keeping it in a sound research track were prominent during the past 3 years.

The Ministry of Health (MoH), especially the Pasteur Institute (PI) provided a great help and motivation by allowing me to access their internal documents such as reports and letters, that deserves a great appreciation at this stage. I should particularly thank Dr. OmidiNia in PI who helped me a lot in facilitating the process of data gathering and also Dr. Dinarvand, the former deputy of this ministry for his open minded approach to support this research.

I have to also thank the Department of Environment (DoE), office of the secretariat of the National Biosafety Committee (NBC) that provided me rich resources of information, such as documents, inter-organizational letters and most importantly the voice recordings of the negotiation sessions. Dr. Jahanshahi as the head of office played a prominent role in this respect.

In addition, the Ministry of Science (MoS) especially the National Institute of Genetic Engineering and Biotechnology (NIGEB) within this ministry facilitated accessing to their internal documents and letters. Especially, I need to thank Dr. Malboobi and Mrs. Esmeel Zade among others.

In addition, the Ministry of Agriculture (MoA) and its Agricultural Biotechnology Research Institute of Iran (ABRII) provided different opportunities for accessing data and information, including letters and reports on biosafety. Dr. Khayam Nekoei, the head of ABRII, and Dr. Salehi deserves great thanks at this stage.

Summary

Vigorous debates have taken place in many European countries, and between the EU and the USA, about regulatory policy regimes covering the assessment and approval of GM crops. In such countries the debates have, to a large extent, taken place in public arenas and with the active participation of broadcast and print media. In Iran, a very vigorous and hotly-contested policy debate concerning legislation covering GM crops took place between 2004 and 2009, but it was almost entirely confined within the Government with no public debate and minimal media coverage. From early 2006 to late 2008 a protracted dispute occurred between different parts of the Iranian regime, which was characterised by an apparent stalemate. In 2008-2009, conspicuous policy shifts occurred, which culminated in the passage of a Biosafety Law by the Iranian Parliament (or Majlis). This thesis describes, analyses and explains the policy-making process from 2006 to 2009. It explains firstly how and why a stalemate arose in the disputes between ministries and departments. It then explains how that *impasse* was overcome, and how a particular policy regime came to be adopted. The chosen analytical framework draws mainly on two bodies of literature, namely the regulation of technological risk, and the analysis of public policy-making. A task-specific analytical framework is developed which uses the concept of the 'framing assumptions', which underpin the particular positions taken by the diverse protagonists in the debate, to analyse the characteristics of the seemingly irresolvable dispute. The differences between those framing assumptions are used to provide an explanation of why the stalemate arose and remained unresolved for several years. The explanation of the eventual policy outcome takes account of those framing assumptions, but on their own they are not sufficient to explain the eventual policy decisions. To provide that explanation, considerations of the unequal division of political power between parts of the Iranian regime are required. The Iranian case study, despite some of its unique characteristics, can support several general conclusions about the dynamics of risk policy making, the conditions under which disputes can arise and those under which they may be resolved.

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List of Abbreviations

ABRII	Agricultural Biotechnology Research Institute of Iran
CBD	Convention on Biological Diversity
CC	Coordinating Committee
CNA	Competent National Authority
CPB	Cartagena Protocol on Biosafety
DoE	Department of Environment
MoA	Ministry of Agriculture
MoH	Ministry of Health
MoS	Ministry of Science
NBC	National Biosafety Committee
NIGEB	National Institute of Genetic Engineering and Biotechnology
NFP	National Focal Point
PI	Pasteur Institute of Iran
RC	Revering Committee

Chapter 1. Introduction

Assessment and management of technological risks has been a hot topic of debate within and between several European countries and between the EU and the USA over the last three decades (Van Zwanenberg and Millstone 2005). Several commentators have analysed those debates according to their adopted theoretical frameworks and the available data (e.g. Murphy and Levidow 2006, Levidow and Carr 2009, Jasanoff 2005, Toke 2004, Millstone et al 2004). A feature of those debates, *inter alia*, especially in the context of the EU, was the role of public and different types of media in affecting changes in the policy discourses, such as considering new scientific uncertainties, acknowledging extra-scientific judgments within regulatory issues, or considering more stringent evidence for safety (Levidow and Murphy 2003).

In the context of developing countries, GM regulation is generally evolving in a different way, because those countries are less engaged in the development and application of modern biotechnology products. Within this context, biotechnology regulation is mainly affected by the provisions of the Cartagena Protocol of Biosafety (CPB) as an amendment to the Convention on Biological Diversity (CBD). The aim of the CPB is the regulation of trans-boundary movements of Living Modified Organisms (LMOs), and its text suggests a precautionary approach. Several studies have analysed the experience of the countries that joined the CPB in developing their national biosafety laws as a basis for their international transactions (e.g. Gupta and Falkner 2006, 2009, Newell 2008). However, this literature has not taken into account or analysed the internal debates and conflicts in those countries in more detail. A small number of recent publications have described the internal processes of developing biosafety laws without providing an explanation of the factors underpinning the disputes (e.g. Karembu et al 2010 on the experience of biosafety law development in Kenya).

A very vigorous dispute emerged in Iran over drafting a biosafety law when the Parliament (Majlis) of Iran ratified the CPB in August 2003. Different Iranian organisations and ministries at that time shared a belief that due to the commitment of Iran to the CPB, and in order to manage the trans-boundary movement of LMOs there would be a need to

draft and adopt a biosafety law. However, those debates mainly manifested in the efforts of the relevant ministries and organisations, chief among them the Ministry of Agriculture (MoA), the Ministry of Health (MoH), the Ministry of Science (MoS) and the Department of Environment (DoE), to take over the location of the office of the secretariat for the National Biosafety Committee (NBC). The NBC was a committee which was established in 2000 from the Ministers of the ministries mentioned above and the head of the DoE, the First Deputy President and three biotechnological experts, and was supposed to play the role of general policy making *vis-à-vis* biosafety.

After several developments and changes to the location of that office, which I will discuss in more detail in the next chapter, the DoE convinced the Cabinet of the necessity of locating the office of the secretariat in that organisation. Shortly after its establishment, in May 2006 the new office located in the DoE invited other ministries to join the negotiations on drafting a biosafety law. According to the available records, the DoE planned to finalise the draft in four sessions to be passed to the NBC, then the Cabinet and lastly to the Parliament for final approval.[1] However, preparing such a draft took nearly one year, amidst increasing debates and disagreements between the Governmental organisations involved. One year was also spent on the approval of this draft by the NBC and the Cabinet. The draft bill was finally sent to Parliament on 5 August 2008 to be passed as the national biosafety law of the country. However, the Agricultural Committee of the Parliament initiated further sessions to negotiate with the previously disputed Governmental organisations to improve the bill. Ironically, the result of that process was the generation of an entirely different draft biosafety law which was eventually passed by the Parliament in May 2009.

The case of GM biosafety regulation in Iran suggests an experience of heated policy controversies between Governmental organisations and ministries, as well as radical policy changes with no public debate, minimal media coverage, and even minimal influence from international actors such as multinational corporations, lobbying groups and other international organisations. Nevertheless, the ratification of the CPB was a driving force in this respect.

[1] Official voice recordings of the coordinating committee sessions, first session on 24 May 2006 (author's translation).

Furthermore, these conflicts are still on-going, as the passage of the law did not resolve the disputes. For example, a senior representative in the MoS in May 2010, a year after passage of the law, accused the office of the secretariat (which is still located in the DoE) of what he called the 'wrong approach' to biosafety and being in opposition to the provisions of the biosafety law of the country. Referring to a prepared draft of rules and instructions for handling, transportation, import and export of GM products, he argued that those instructions were absolutely unjustifiable because they presumed the modified organisms were like untreatable diseases.[2]

Therefore, the case of Iran provides an example of enduring policy controversies as well as policy shifts at the level of Governmental organisations without public debate, media coverage or the influence of international actors (excepting the CPB) affecting its policy agenda. The topic of this dissertation is the analysis of the experience of Iran in developing GM biosafety law, and the aim of this research is twofold: analysing policy controversies and policy changes together by posing this general question:

How is it possible to analyse and explain the policy controversies as well as the policy changes in the biosafety regulation processes of Iran within which there were neither public involvement nor media coverage, nor a considerable international force?

From the policy point of view, this analysis is very important, as the controversies have not been resolved even following the passage of the law by the Parliament, and the protagonists in the system are still struggling with their predicament. More theoretically, this study could be interesting because it discusses a case of biotechnology and risk regulation in an entirely different context from those discussed in the published analytical literature (e.g. Murphy and Levidow 2006, Millstone et al 2008, Jasanoff 2005 on industrialized countries, or Gupta and Falkner, Keeley 2006, Newell 2008 on developing countries).

However, it is necessary to base my research on a sound theoretical framework in order to be able to analyse the case in hand. For this purpose, I will extensively use two broad streams of literature as follows: 1) biotechnology risk regulation, and 2) public policy

[2] http://mehrnews.com/fa/NewsDetail.aspx?&NewsID=1084353

analysis, mainly because both of them are relevant to the current experience of Iran, and could offer useful tools and insights for the purpose of this research. Before appraising this literature, in the next chapter I will cast more light on the context of the study, i.e. Iran, as a country that might not be well known. In the same chapter I will also review the international context of biotechnology regulation, including both the experience of more advanced countries such the USA and Europe, along with other developing countries which have been discussed in the literature in the light of their commitments to the CPB.

In Chapter 3 I will review the useful tools of the mentioned two streams of literature to identify the theoretical standpoints of this research that in turn will help me to develop a useful theoretical framework for the purpose of the analysis in Chapter 4. Throughout Chapters 5-7, I will discuss the three phases of negotiations for drafting the biosafety law in chronological order in order to investigate the factors underpinning both policy controversies and policy changes. Finally, I will discuss the findings and implications of this research both in terms of its theoretical and empirical contributions in Chapter 8.

Chapter 2. Context of Study

2.1. Introduction

The aim of this chapter is to provide an overall picture of the context within which the intricate policy process of regulating biosafety in Iran has been taking place. This background picture, along with the theoretical insights from the next chapter, should provide a good basis from which to develop a theoretical framework and research methodology.

As a developing and a less discussed, and perhaps more unknown country, I will provide a general picture of the political structure of Iran and the normal process of legislation within it. Then I will highlight the institutional character of science, particularly biotechnology. Reviewing the international context of GM regulation, including some debates across Europe and those between the USA and the EU, as well as the context of developing countries will be the topic of the following two sections. Then I will turn to a chronological history of biosafety regulation in Iran, which will be helpful in delineating the overall processes and different stages of negotiations. This information should provide an overall picture of the Iranian context and the biotechnology legislation process located in an international context.

2.2. The Political Structure in Iran

2.2.1. General Political Structure

When mentioning Iran, I refer to the Islamic Republic of Iran since the revolution in 1979. Although Iranian people share a long-standing cultural tradition over a history of more than 2500 years, the new political structure of Iran emerged after that revolution and mainly under an Islamic ideology. The new governance system is shaped around a central principle called "Vellayat Faghih", denoting the delegation of power from God to man through a certain route. On this basis, the Supreme Leader is the highest authority in the governance system, responsible for delineation and supervision of the general policies of the country according to the Constitution. There are three bodies in connection with the Supreme Leader, which are mainly constituted to fulfil the monitoring roles of

Supreme Leader: the Assembly of Experts, the Council of Guardians and the Expediency Council.

The Assembly of Experts chooses the Supreme Leader and monitors his activities. The members of this assembly are virtuous and learned clerics, chosen every five years in a countrywide election. After the first Supreme Leader of Iran, Ayatollah Khomeini, passed away in 1989, the Assembly of Experts chose Ayatollah Ali Khamenei as the Supreme Leader of Iran, who has been in this position ever since.

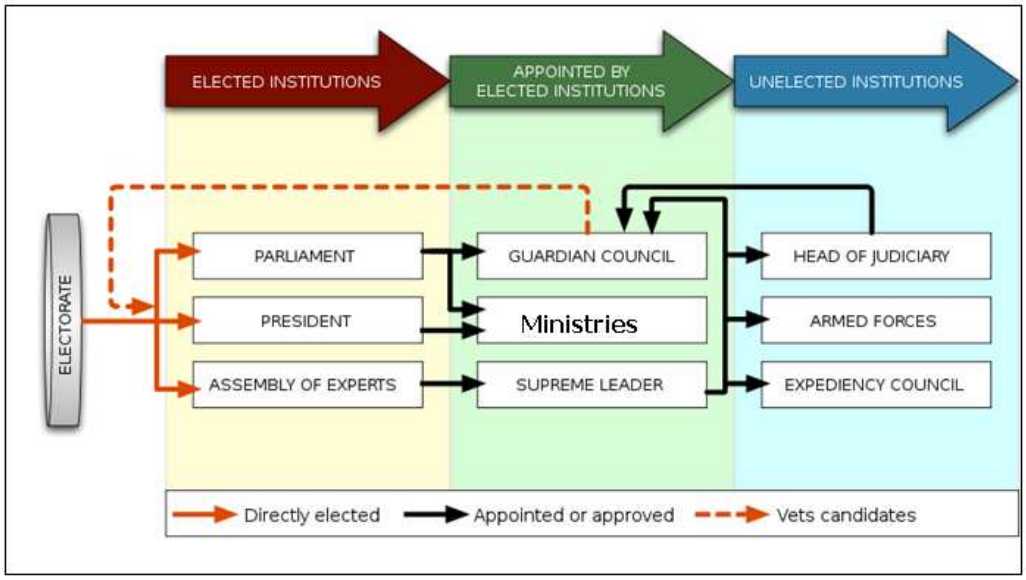
The Council of Guardians, as the second body connected to the Supreme Leader, is constituted from six clerics chosen by the Supreme Leader and six other members elected by the Iranian Parliament (Majlis). This council checks that the legislation of the Parliament is in line with Islamic rules and with the Constitution, and in the case of contradiction, it returns the law to Parliament for the necessary modifications. This council must also approve the general competencies of nominees for either presidential or parliamentary elections (both of which are also countrywide elections). The Expediency Council, the third body related to the Supreme Leader, is responsible for resolving conflicts between the Parliament and the Council of Guardians whenever the Parliament insists on its passed laws and the Council of Guardians emphasises mismatches between the passed law and the Islamic rules or the Constitution. On those occasions, the Expediency Council takes the final decision.

Along with these three controlling institutions connected to the Supreme Leader, there are three important authoritative bodies, which are the Government, the Parliament and the Judicial System. The President, as the head of Government, is mainly responsible for Government policy-making and implementing the Constitution and executing other rules and legislation. The President sends to the Parliament the list of his favoured persons as suggested Ministers for every new Governmental period, i.e. every four years. Parliament will investigate their general competencies and can refuse to accept them. In this sense, Ministers are chosen through an interaction between the Parliament and the President.

The Parliament is also in command of drafting legislation, approving budgets and ratifying international commitments. Iranian people participate in two different and

independent elections, each one every four years, though not at the same time, to choose the President and Parliament members. The third important power in Iran is the Judiciary System, the head of which is chosen by the Supreme Leader. The following picture is adapted from Wikipedia and represents the political structure of Iran (Figure 2-1).

Figure 2- 1 Political structure of the Islamic Republic of Iran



Source: Adapted and modified from Wikipedia[3]

Figure 2-1 indicates that the population elects the MPs, the President and the Assembly of Experts. The Assembly of Experts chooses the Supreme Leader and the Supreme Leader has a large influence on selecting other authorities, including the head of the Judicial System, the Army, half of the members of the Council of Guardians and the Expediency Council. Ministers are chosen in an interaction between the President and the Parliament.

2.2.2. Process of Legislation

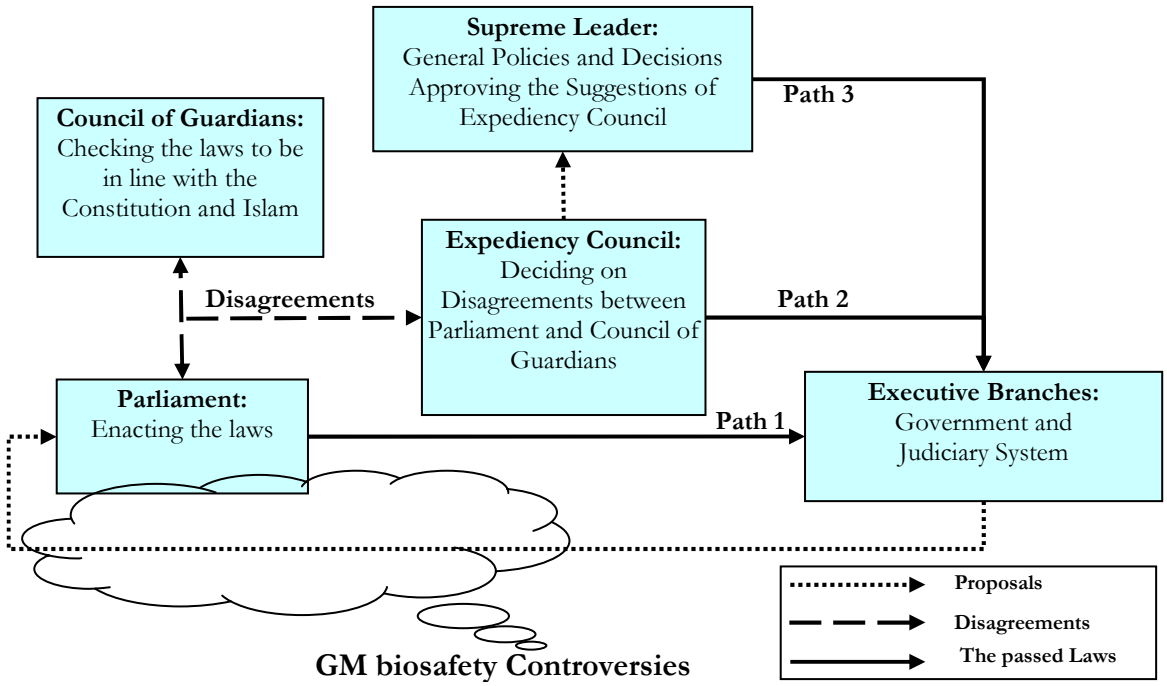
The process of legislation in Iran is somewhat intricate because different bodies in the country are involved in it (see Figure 2-2). The highest power is the Supreme Leader who can make rules and decisions above other authorities. The Expediency Council is composed of the national experts selected by the Supreme Leader and is also responsible

[3] http://en.wikipedia.org/wiki/File:Iran_gov_power_structure.svg

for devising general policies of the country. The suggested policies of this council, after the approval of the Supreme Leader, will come into force (Path 3 in Figure 2-2). .

The Expediency Council also has another role in legislating. In the case of disagreements between the Parliament and the Council of Guardians, in which the Council of Guardians rejects a law but the Parliament insists on that law, the Expediency Council is the final decision-maker. Thus, its decisions in cases of disagreement would be final, as shown in Path 2 in Figure 2-2. However, the normal path of introducing new laws comes through the Parliament as the main legislature in the country.

Figure 2- 2 Legislation process in Iran from three different paths, and the position of controversies over biosafety



However, the general and ordinary path of legislation is Path 1, while the two others take place only occasionally. As we will see in the story of biosafety regulation in this chapter, biosafety legislation had nothing to do with Paths 2 or 3, instead moving along the dashed line as the input to the Parliament, to come across Path 1 and the main controversies emerging in preparing an acceptable draft by the Government and between Governmental Ministries and organisations, almost behind closed doors.

2.2.3. Government and Politics

The range of perspectives in Iran *vis-à-vis* governance and ordering society is very diverse. The 30 years of recent history of the country could be divided into four main eras based on the perspectives of the ruling Governments. The first period dates from 1982 to 1990, when Ayatollah Ali Khamenei was the President, followed by the second period, encompassing eight years under Ali Akbar Rafsanjani's Government and then the third period, President Khatami's Presidential term for eight years until 2004. Since then, Mahmoud Ahmadi Nejad has been the Iranian President.

Apart from the first eight-year period, during which considerable disagreements arose between the President and the Prime Minister of the time, Mr Mir Hussein Mousavi, the other Governments experienced a more stable situation in terms of intra-Governmental conflicts, as the position of Prime Minister was eliminated from the Constitution in 1990.

Although all Iran's Presidents believe in Islam and the Constitution, their approaches to administrating the country and the important issues the Government should consider have differed. Consequently, new Presidents normally change most of the administrative officials as well as the medium-level managers in the country to be in-line with their own perspectives. These substantial periodic changes resemble a paradigmatic pattern in the Iranian system: eight years of stability followed by a major political change as the result of the changing of President. For the three most recent Presidents of Iran, three dispositions could be separated as follows: economic development as the main agenda in President Rafsanjani's time; political development and the importance of liberty and freedom in President Khatami's Government; and developing justice in the period of President Ahmadi Nejad.

There is no structured and organised political party in Iran. Although President Khatami began work to institutionalise political parties in the country, substantial disagreements within the country and from different influential groups meant those efforts achieved little. The upshot of Khatami's administrative period was a diverse and incoherent political perspective referred to as 'reformist', holding different views under one flag,

along with another broad perspective, but not a party, named 'conservative'. Intriguingly, Dr Ahmadi Nejad won the first round of the ninth Iranian election in 2005 without any connection to these semi-parties or groups. However, conservatives almost all supported him in the second round of the 2005 election when he won the contest against Ayatollah Rafsanjani, the former President. Thereafter, President Ahmadi Nejad has strongly rejected the essentiality and importance of political parties for the Iranian political system.

2.2.4. Cabinet

The Cabinet of Iran is composed of 21 Ministries as well as 13 Deputy Presidents, including a first Deputy President, the head of which would be the chair of the Cabinet in the absence of the President. Regarding the case of biosafety regulation in Iran, as I will discuss in the chronological history of that process at the end of this chapter, the main involved organisations were the Ministry of Agriculture (MoA), the Ministry of Health (MoH), the Ministry of Science (MoS) and the Department of Environment (DoE). The DoE is not a Ministry, but an organisation in the Government, the head of which is a Deputy President and therefore a member of the Cabinet, with a similar political rank to other Ministers.

2.3. Institutionalisation of Science in Iran

A discussion of the institutionalisation of science in Iran, especially biotechnology, would help in giving a clearer picture of the circumstance in which the Governmental organisations debated over the biosafety law of the country. For the purpose of this section, I will review the institutionalisation of science in ancient Iran, followed by the challenges in the institutionalisation of science in modern Iran, which is still emerging, in comparison to the most advanced countries, and the specific circumstances of biotechnology in this context.

2.3.1. The State of Science in Ancient Iran

Iran's history is replete with stories of outstanding scholars in various scientific fields such as mathematics, chemistry, astronomy and medicine. The variety of disciplines was not confined to the sciences, but also included philosophy, literature, arts, social sciences, and

what was referred to as applied philosophy, including management, at the levels of Government and the family, as well as professional engagement in religious thought.

Iranian scholars historically tried to capture a variety of disciplines, attempting to apply them in their social lives, aiming at improving the state of society. Therefore, these scholars had social roles along with their personal expertise, as well as practical wisdom, which in turn pushed them to become social references and problem solvers for ordinary people in terms of family problems, religious orders, children's training and so on. Although scientific activities were mainly conducted by individual researchers driven by their personal interests, not in well-established institutes, Iranian people always respected their scholars for their considerable impacts on society. To name just two, Khayyam, a famous mathematician, astronomer, physician and poet, and al-Khwarismi, a great mathematician, astronomer and geographer both played significant roles in developing science in ancient Iran (Nasr 2006).

The position of scholars in the history of Iran's dynasties was also prominent. It was imperative for many kings to have a consultant from among those highly-respected scholars, even if just to give them a formal position to pretend that they considered the importance of wisdom in administrating society. In retrospect, many intellectuals also used the resources that came from the kings, at the cost of providing a physical presence in some sessions and ceremonies. Nevertheless, there were some kings who truly based their decision-making systems on the opinions of scholars for the sake of improving the state of society. Among many Iranian intellectuals, we can cite Ibn Sina, Sheikh Tusi and Nizam al Molk as famous scholars who had substantial influences on political decision making (Ibid).

To sum up, Iranian ancient history *vis-à-vis* science could be characterised, among other things, by the prominent role of individual scholars in developing knowledge, including science, who had established purposeful linkages with both dynasties and society based on their personal capabilities in a time when knowledge production was not institutionalised.

2.3.2. Science and University in Modern Iran

The institutionalisation of scientific activities was the result of borrowing from the experiences of the West, and especially Europe, in its successful organisation of science and research. In the 16th century, when the institutionalisation and subsequent flourishing of the sciences started in the West, the interactions between Iran and some European countries began. On this basis, several Europeans travelled to Iran, and some Iranian scholars and kings also travelled to Europe. For instance, in the period of Shah[4] Abbas II from 1642-1666, there were many interactions between Iran and the West, especially Great Britain (Fisher 1968).

However, those interactions did not lead to the imitation of modern institutions of science from the West until 1852, when Amir Kabir, the chief Minister of the Qajar Dynasty established a new school called Darolfonun[5] by inviting Western scholars (initially Austrians, followed by Italians, French and Germans) to educate the Iranian candidates (Molavi 2005). Decades later, in 1934, this school was transformed into the University of Tehran as a formal institution for science education, with fewer concerns about technical applications. Thereafter, several other universities were established with the spirit of science education, such as the University of Tabriz in 1947, the University of Mashad in 1949, and the University of Isfahan in 1950, followed by several other universities in Tehran and other cities, all supported by the Government without charging students tuition fees. In this respect, the contribution of science to industry remained limited, as universities took on the role of education rather than research and application.

Pursuant to this institutionalising process, universities replaced the previous individual knowledge working activities of traditional scholars, while having less impact on the production of useful knowledge, and fewer concerns regarding applications of knowledge. Moreover, the concept of science as a modern entity which refers to experimental inquiries was translated as *elm* in Farsi. *Elm* is a historical word indicating 'knowing' in general without conferring any distinction between natural sciences, social sciences,

[4] 'Shah' means king.
[5] 'Darolfonun' means 'the house of techniques'.

medicine and engineering. A result of these institutional evolutions was the inducement of a highly positive perspective among the Iranian people of science, and of university as the context of learning science. In this respect, engineering is considered as having a special status, followed by medicine, basic sciences, and then social sciences.[6] Other forms of knowledge, such as arts, music and sports, are considered by society as the lowest priorities (Mohseni, 2000). Hence, this background makes it more understandable why in current Iranian society, having a family full of university-educated children and relatives, especially in scientific disciplines (engineering, medicine, basic sciences and then social sciences and humanities), is highly respected (Shabanloo 2001, Marjaei 2004).

The importance of universities in the Iranian system was reflected in the construction of a specific Ministry for higher education in 1967, which was named the Ministry of Science and Higher Education. This Ministry was supposed to deal with the affairs of Government-led universities until 2000, when its name was changed to the Ministry of Science, Research and Technology (hereafter referred to as the MoS). However, it still mainly deals with education rather than science and technology development in the country, partly because of its institutional history. The former name of this Ministry and even its current activities are a reflection of the fact that in the context of Iran, universities are supposed to be places for teaching and education, or places for learning science, rather than places for research and development.

The speed of establishing new universities accelerated after the Islamic revolution in 1979, both through increasing the number of Government-led universities and by initiating 'open' universities working based on charging tuition fees, as well as another type of part-time university named 'Payam Noor'. This post-1979 expansion also included increasing the number of disciplines and students in each university, mainly in conjunction with increasing the total number of university candidates. As the Governmental universities had a limited capacity, many families have been compelled to pay the tuition fees of 'open' and Payam Noor universities for the sake of having educated children, with perhaps better jobs and positions in the future.

[6] However, the social sciences are also different; for instance, sociology and philosophy are considered much better than history or geography.

The prestige and importance of science in the Government went beyond the boundaries of the former Ministry of Science and Higher Education when other Ministries started to develop their own research laboratories in different scientific and technological fields, mainly after the Islamic revolution in 1979, to carry out applied research and to provide useful insights for the managers in their decision making.

To list just a few, the Ministry of Energy has run the Niroo Research Institute (NRI) since 1982 to improve decision making and to conduct research. The Building and Housing Research Centre (BHRC) is a large organisation in the Ministry of Housing and Urban Development which has conducted necessary research into related issues since 1979. Even the MoS tried to provide a sound foundation for its decision making through initiating the National Research Institute for Science Policy (NRISP) in 1980. When surfing the web, it is not difficult to find several other Iranian research institutions, which are supposed to carry out sophisticated applied and developmental research and help Ministries to reach better decisions.

In short, modern science has been welcomed by Iranian society and is institutionalised both in universities that mainly take on the job of teaching, rather than research, and in Governmental laboratories and research centres, which are expected to be involved more in applied research. However, there is another important type of body involved in knowledge and technology production: private companies, the roles and impacts of which differ sector by sector. In the next section I will discuss the institutional context of biotechnology by considering the sector-specific conditions of private firms.

2.3.3. Institutional Context of Biotechnology Science

Large Governmental research centres are the key players in developing biotechnology in Iran, while the universities are mainly involved in teaching and education. In addition, there is a small private sector in Iran which is not involved in biotech research and development activities. This situation has opened up a great opportunity for Governmental bodies to lead the research activities to develop biotechnological science and technology within the country. In the absence of a significant private sector and the

lack of sufficient research facilities within universities, these research institutes shape the core of Iranian biotechnology research and knowledge.

Table 2- 1 Characteristics of Agro-Medical Biotechnology in Iran

Indicators	By the date: October 2008
Number of Researchers (PhD & MSc)	1750
Total Number of International Research Papers	700
Total Number of International Patents	5
Total Number of National Patents	80
Total Number of Centres Doing Research About Biotechnology	93

Source: National Biotechnology Development Plan, revised 2009[7]

Table 2-1 summarises some characteristics of biotechnology in Iran. Regarding the number of researchers (1750), considering that the population of Iran is more than 70 million, the number of researchers in biotech per million population is nearly 27, while the average of the total number of researchers in Iran in 2001 was 405 (SCRC 2005). Some recent sources suggest that this number is near 1000 for 2011[8]. This means that the number of researchers per million population in biotechnology in 2008 in comparison to the total average of researchers in 2011 is less than 3 % (27 out of 1000). This is even fewer than the number of researchers in some other high-tech fields in Iran, such as nano-technology, for which the available data show nearly 6700 registered researchers in 2009.[9] Overall, those figures would suggest that the number of researchers in high-tech fields (and especially bio-tech and nano-tech) are conspicuously low.

In terms of the number of international papers, although it is not clear from the table whether journals or both journals and conferences are included, a comparison with the total numbers of international journal papers is illuminating. There were 700 publications in biotechnology-related fields in Iran between 2001 and 2008, in comparison to the total number of international papers in Iran over the same period which is nearly 57000, yielding a proportion of less than 1.25%.[10] This figure for the total papers published in nano-technology is fewer than 1400, which is about double for the figure for

[7] Adapted from the national biotechnology development plan drafted in 2004 and revised in 2009. The former version was published in 2006 and the new one is not yet published. I was able to access a copy of an unofficial version of this new document.
[8] http://www.jahannews.com/vdcc14qs02bqe18.ala2.html (Head of secretariat of the High Council of Cultural Revolution)
[9] http://www.nano.ir/sub_forsight.php?page=main_policy&subPage=9 (Secretariat of the Iranian nano-technology initiative council)
[10] http://www.hamshahri.org/print-86563.aspx (this page reported the number of publications from 2001 and by summing the numbers for each year, total numbers would be around 57000)

biotechnology papers.[11] Considering the number of patents, while the sum of the patents in biotech (agro-med) up to 2008 was 80, the total number of patents in 2008 alone in Iran was near 10000.[12] That means that the aggregate number of patents in biotech up to 2008 is 0.8% of the number of total patents of 2008 alone. No patent data are available for nano-technology in Iran.

These measures indicate that biotechnology is not well established in the country and is still in the early stages of development in comparison to other fields. Nevertheless, although biotechnology is not yet well developed, it has been considered as a high priority for development in different long-term plans for the country, such as the National Vision 2025, which was stipulated by the Supreme Leader in 2005.[13]

Table 2- 2 Share of the private sector in biotechnology development

Indicators	By the date October 2008
Share in production of equipment and products	Near 55 %
Role in research activities	Negligible

Source: National Biotechnology Development Plan, revised 2009[14]

Scrutinising the role of private firms in biotechnology (Table 2-2) reveals that these companies are only involved in producing facilities and some products, without undertaking considerable research. Put differently, they are not involved in developing biotechnology. These figures suggest that the main research activities are concentrated in the Governmental research centres, which is the topic of the next section.

2.3.4. Large Governmental research centres

In the absence of private firms, different Ministries have undertaken the job of research and development in biotechnology. The MoA established the Agricultural Biotechnology Research Institute of Iran (ABRII) in 2000 through consolidating all related research activities in this Ministry. A variety of GM rice had been developed in this research centre

[11] See footnote 9
[12] http://www.jamejamonline.ir/newstext.aspx?newsnum=100903549658
[13] The text of the National Vision 2025 is available at http://www.dolat.ir/PDF/20years.pdf, albeit in Farsi.
[14] See Footnote 7

by 2005.[15] The Pasteur Institute (PI) of Iran is a major research centre of the MoH, which formerly was a national centre of human infectious diseases research, working on diagnosis and vaccine production from 1920. The Biotechnology Research Centre (BRC) of the Pasteur Institute of Iran was established in 1993, with the goal of initiating biotechnology-related research and is currently the largest department of the Pasteur Institute. The National Institute for Genetic Engineering and Biotechnology (NIGEB) was established in 1989 as a part of the MoS's mission to develop scientific knowledge in the field of biotechnology. ABRII conducts agricultural biotechnology research activities (green biotechnology), PI concentrates on pharmaceuticals (red biotechnology), while NIGEB works on both types of biotechnological research (red and green).

These institutions were historically interested in biosafety because of their developing roles and responsibilities. As the historical account of biosafety at the end of this chapter will show, the scientists or responsible bodies in these institutions have been involved in biosafety since 2001 when Iran signed the Cartagena Protocol on Biosafety (CPB). However, their engagement in the process of drafting the biosafety law started in April 2006, when the DoE invited the MoS, MoH and MoA to send senior representatives to join together and start the negotiations, known as the Coordinating Committee (CC) discussions, for drafting the biosafety bill. In response, these Ministries referred to their research centres as the capable institutions and the above three biotechnological centres selected three biotechnologists to represent their opinions in the CC sessions.

Before providing a detailed picture of the historical evolution of biosafety regulation in Iran, it is worth looking at the broader international context within which regulation of GMOs takes place. On the one hand, there is a context in which more technologically advanced countries like the USA and the members of the EU are characterised by a diversity of approaches to the regulation of GMOs, while on the other hand, less technologically advanced countries have developed Biosafety legislation under the influence of the CPB as the most important international treaty affecting their domestic biotechnology regimes. I will discuss both contexts in the following sections.

[15] More detail of this event will come in the chronological history of biosafety at the end of this chapter

2.4. Debates across the EU and the USA on Agricultural Biotechnology

Regulation of technological risk has been high on the agendas of most of the advanced countries because of their rapid technological development (Jasanoff 1986). In this sense, biotechnology is a case of a new technology that was noticed by policy makers in the 1990s as a technology that might need special attention and regulation. The debates within those countries were mostly shaped around the experiences of risk assessment rather than provision of a comprehensive GM law. I will discuss the models developed for risk regulation in the next chapter, while in this part I will concentrate on the experiences of those jurisdictions and the disputes among them.

The EU chose to develop a unified approach *vis-à-vis* biotechnology regulation to establish a harmonised system across the member states. The Directive 90/220 stated that each country should set its regulations for avoiding adverse effects (EEC 1990). The EU regulatory model continued to be a national level regulatory system until 1997 and based on a precautionary principle treating GMOs under separate processes, and without any requirement for labelling (Tiberghien 2009).

But this regulatory regime could not continue to survive under the extreme pressure from public and media calling for a more stringent system. In 1997, directive 97/35 was introduced as Annex III of directive 90/220 that made the labelling of novel foods compulsory (Carson and Lee 2005). Public disputes erupted in 1999 with serious moratorium on GMOs in 2000 (Kleinman et al 2009).

Levidow and Murphy (2003) discuss the trend that managed in the EU as a result of public involvement in the regulatory debates as:

- Considering more and new scientific uncertainties highlighted in public-scientific debates
- Acknowledgement of extra-scientific judgements within regulatory issues and expert advice by regulatory bodies
- More stringency of the criteria for evidence of safety, especially concerning environmental norms and the causal pathways of potential harm.

In the UK, the public exerted tremendous pressure on the Government against the approval of GM crops, while on the other hand, industry did its best to convince the public and the Government that there was no basis for concern about such products. The Government on the one hand tended to develop and promote R&D activities and on the other hand had to meet the concerns of the public (Levidow and Carr 2000a). Among the debates in the context of the UK, the problem of defining what counts as an adverse effect was one of the most serious issues, in that the public requested scientists and regulators to consider a broader definition of risks to include a wider range of possible adverse effects and to take into account more evidence in their assessments (Levidow 1999).

France also experienced a high level of public engagement in the issues over biotechnology regulation and risk assessment. One of the results of public involvement was the criticism of the regulatory advisors and the broadening of scientific disciplines other than molecular biology. The French Government tried to open up the discourse to include experts and non-expert lay public representatives (Roy and Joly 2000). Subsequent developments and the related ups and downs mainly came from changing political systems in this country.

Although the German Government faced a high degree of opposition from the public in developing and marketing the GM crops, it did not consider participatory approaches like the UK or France. Instead, the Government emphasised the necessity of prioritising scientific advice over politics, which in turn generated a gap between the Government and the public. In reaction, consumers boycotted GM products, which in turn produced a blockage for commercialising those products (Dreyer and Gill 2000).

In the context of the USA, the disputes revolved around the concept of novelty to determine what genetic combinations should be classified as novel and what novel effects need regulatory controls (Levidow and Carr 2000b). However, the USA did not face the same amount of public dispute as Europe did. The disputes in the USA were mainly portrayed as scientific disputes (Jasanoff 1992). This is what Jasanoff describes as the "product view" in the USA, in comparison to the "product and process" views popular in

the UK. While the former is concerned with GM products and whether or not they should be considered substantially novel, the latter is concerned with the possible risks of both GM products and the processes involved in developing GM crops (Jasanoff 1995).

Levidow and Murphy summarise the principal assumptions of the USA's system as: "four key 'principles' or assumptions:

- the products of recombinant DNA technology will not differ fundamentally from unmodified organisms or from conventional products;
- existing laws are adequate to regulate the products of this technology;
- products, not processes, should be regulated, and regulation should be risk-based;
- regulation should be directed toward the intended end use for products, and should be conducted on a case-by-case basis." (Levidow and Murphy 2002 p. 3)

The differences between those broad official assumptions in the USA and the precautionary approach in the EU have been counted as important factors in shaping the transatlantic controversies (Millstone et al 2004). In this sense, even the concept of "substantial equivalence" (OECD 1993) could not overcome the differences. This concept was largely accepted in the assumptions of the USA's system, and was then adopted in 1997 by the EU in its Novel Food Regulation 258/97, which in turn increased the hope for a convergence in transatlantic GM regulation.

Nevertheless, the European people did not accept the idea of substantial equivalence as a sufficient measure of safety. As a reaction, the public seriously opposed USA exports of GM soya in 1997 (Levidow and Carr 2000b). In response to these disputes, the Genetic Engineering Alliance asked for a "five year freeze" on all commercial use or patenting of these products in the European context (GEA 1999).

The concept of substantial equivalence was also criticised by various scholars, including Millstone et al (1999). This concept was originally introduced by OECD as a type of pre-market assessment of GM products, suggesting that when GM crops or foods are similar in their chemical analyses, nutritional content and allergenic properties, then no further safety assessment would be required. The OECD document set it as: "if a new

food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. No additional safety concerns would be expected. Where substantial equivalence is more difficult to establish because the food or food component is either less well-known or totally new, then the identified differences, or the new characteristics, should be the focus of further safety considerations (OECD, 1993: 13).

Such criticism in turn caused a quick response by the OECD (Kearns and Mayers 1999). Debates continued until the EU finally downgraded the concept in 2001, stating that "this proposal does not include a notification (simplified) procedure as laid down in Regulation EC No 258/97 on novel foods and novel food ingredients for genetically modified foods which are substantially equivalent to existing foods." (CEC 2001) The earlier European Directive 90/220 was replaced by 2001/18, which widened the scope of required risk assessments to extend from direct and short-term effects to also include long-term and indirect effects. On the other side of the Atlantic, the USA had more tentative changes than the EU, though it modified the view that GM products do not present unique safety concerns (Levidow and Murphy 2002).

Overall, there were several disputes and controversies on both sides of the Atlantic over the regulation of GM crops, especially after 1999 when Europe stopped approving GM products but the USA continued to commercialise new GM products, which in turn increased the regulatory gap between those jurisdictions to the point that the USA took a case to the World Trade Organization (Murphy and Levidow 2006).[16]

Among the structural characteristics of the debates, we can note the conspicuous eminent role of the public in the context of Europe as well as the active participation of private corporations on both sides of the Atlantic. Murphy and Levidow argue that three dialogues broadly shaped the conflicts between those jurisdictions, namely the Transatlantic Business Dialogue promoting trade liberalisation in a harmonised way, the Transatlantic Consumer Dialogue emphasising the right of the consumer to know about

[16] An extended analysis of the EU-US conflicts can be found in Murphy and Levidow's (2006) book titled *Governing the transatlantic conflict over agricultural biotechnology: contending coalitions, trade liberalisation and standard setting*. The authors also consider transatlantic cooperation as well as the intra-jurisdictional conflicts associated with the transatlantic conflicts to provide a richer explanation of how the two played a role in shaping the transatlantic conflicts.

products and to choose among them, and the Transatlantic Environmental Dialogue demanding prior proof of safety for GM products (ibid).

I will discuss the useful theoretical insights of the literature on biotechnology regulation in the context of advanced countries in the next two chapters, but it is important to note that the disputes were not around developing a biosafety law, but approving and commercialising certain GM products based on the procedures of risk assessment and risk management. Further, those disputes emerged in an entirely dissimilar context in comparison to the context of Iran, which is different because there was no public dispute, minimal media coverage and less international pressure (ultimately the commitment of Iran to the CPB), as well as the absence of a considerable private profit-seeking sector.

2.5. Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety (CPB) is an international treaty aimed to regulate the trans-boundary movements of Living Modified Organisms (LMOs). This protocol was added to the Convention on Biological Diversity (CBD) on 29 January 2000 as an environmental treaty to protect biological diversity from the potential risks of LMOs resulting from modern biotechnology. The protocol came into force on 11 September 2003. The protocol is written according to a precautionary approach and developed a process of information exchange between countries to facilitate the trans-boundary movement of these products through providing information in advance about the characteristics of the products to be imported.[17] Iran signed the text of the protocol in 2001 and the Parliament of Iran ratified it in August 2003.

Article 2 of the protocol, Acts 1 and 2 emphasised:[18]

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.
2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that

[17] More complete information about this protocol is available on its website at http://bch.cbd.int/protocol/background/
[18] http://bch.cbd.int/protocol/text/article.shtml?a=cpb-02

> prevents or reduces the risks to biological diversity, taking also into account risks to human health.

Act 1 of this article requires member states to take necessary measures to implement their obligations, chief among them, as suggested in Act 2, is protecting the environment by reducing risks to biodiversity. Nevertheless, it does not set or require particular criteria for risk assessments and risk management, nor does it specify some universal rules or procedures for risk assessment. The protocol empowers states to restrict imports of LMOs based on their internal regulatory measures, and importer countries can ask for further evidences from exporter agent (company or country) to inform assessments of the risk of LMOs according to their internal biosafety regime. As a result, although members of CPB need to set their internal rules and regulations by considering the requirements of protecting environment and biodiversity, they are not obliged to follow a particular way.

Therefore, several countries started to enact their internal biosafety laws in order to ensure that they monitor and control the possible, and mainly environmental, adverse effects of LMOs. One of the main concerns of many commentators and scholars was to understand and even estimate the extent to which the CPB could contribute to harmonizing the regulatory regimes of member states, given the fact that the protocol provides little specific legislative or regulatory guidance apart from permitting not more than the adoption of a precautionary approach.

Subsequently, various scholars started to analyse the impacts of this protocol on the member countries to discuss whether or not the CPB imposed regulatory limitations that in turn may lead to regulatory convergence or whether it opened considerable opportunities for regulatory divergence. In a conceptual paper, Jaffe (2005) criticised the CPB for its insufficiency in providing clear guidance for the member countries, which in his view would lead to a diversity of national rules and regulations. Millstone and Van Zwanenberg (2003) argued that the hope for convergent regulatory procedures for agricultural biotechnology might not be realised because of the local nature of regulation in different countries and the uncertain and equivocal character of science. They discuss

further the degree of autonomy developing countries could exercise in light of accepting the CPB and the WTO.

Gupta and Falkner (2006) discussed the variety of avenues the CPB had opened for its member countries in biosafety regulation, and the different ways that Mexico, China and South Africa have been using these possibilities in practice. However, they claimed that studying the cases of those three countries would raise the hope for a more convergent regulatory regime across member states. As a general pattern, Gupta and Falkner argued that although Mexico, China and South Africa had set up ambitious plans for developing biotechnology, ratifying the CPB had contributed to changing their policy discourses to adopt a more precautionary approach than had previously been the case. They even tried to generalise the conclusion of their study by forecasting a similar trend in other members of the CPB in the future.

Newell (2008) also analysed how China and India had moved toward more precautionary approaches because of their commitments to the CPB. He analyses the different ways those two countries translated their commitments to the CPB into their national policies amidst increasing pressure from multinational firms forcing them to make less restrictive rules and regulations. Falkner (2006) also argues that China has witnessed a great transformation in its environmental policies from a strongly promotional to a more precautionary approach because of its involvement in the CPB. Nevertheless, changes are continuing in this country.

In addition, there are a few studies about the CPB that tried to analyse other aspects of this international treaty. For instance, Morris (2008) highlights a problem with the CPB in its lack of alignment with some local agreements amongst African countries. From this perspective, Morris discussed how possible differences could jeopardise the success of the CPB in those African countries.

In short, the mainstream literature about the CPB is mainly concerned with the impacts of this protocol on the regulations of the member states with less consideration of their internal policy making experiences or possible conflicts and disputes that might contribute to those policy consequences. The CPB was also a starting point for regulation

of biosafety in Iran and I will review a chronological history of its evolution in Iran in the following section. However, the final biosafety law of Iran was enacted with minimal attention to the provisions of this protocol, and consequently it may provides a counter-example to those studies that suggest that the CPB may be an international source of convergence amongst regulatory regime (eg Gupta and Falkner 2006). It seems that for a better understanding the policy outcome in Iran, internal policy processes should be taken into account, which is the main concern of this research. This thesis analyses that controversial policy process, the changes of the policy outputs at different stages and the factors that might contribute understanding those developments.

2.6. A chronological history of biosafety policy making in Iran

The history of biosafety in Iran can be divided into two main parts: before and after 2006, when the formal negotiations for drafting the bill started. The first period includes the early, mostly individual Ministerial and organisational activities, and the consequent evolution and challenges over the location of the office of the secretariat of the National Biosafety Committee (NBC). The task of preparing the draft of the bill did not formally start during this period. I will elaborate on this process in the following paragraphs. In 2006, the second period started when the DoE, as the latest location of the office of the secretariat, invited other involved Ministries to take part in the sessions for negotiating and finalising a draft bill for the biosafety law. In this period there were no structural changes such as changes in the location of the office of the secretariat for the NBC or the organisations involved in the NBC committee and the process of negotiations.

2.6.1. A Brief History of the first period of Biosafety policy making before 2006

It seems that the first activities *vis-à-vis* biosafety started in 1999 (i.e. during President Khatami's Government) when a five-page biosafety draft text was suggested by the DoE to the Cabinet.[19] At that time, the aim of the DoE was to take an initiative from Cabinet in relation to biosafety. However, it faced serious opposition from the MoA, MoH and MoS as well as from their biotech research institutions. In 2000, following a new decision by the President, the National Biosafety Committee (NBC) was established, composed of

[19] Interview with the senior representative of the MoS on 5th of July 2008.

the MoH, MoS, MoA and the Ministry of Trade (MoT), as well as the DoE and three biotechnological experts chosen by the President. The aim was to provide a basis for the future needs of the county *vis-à-vis* biotechnology regulations. During that time, the NBC decided to locate the office of its secretariat in the MoS, and more specifically in the National Institute of Genetic Engineering and Biotechnology (NIGEB). Subsequently, Iran signed the CPB in 2001.

During that time, the secretariat in the MoS did not invite other organisations for negotiations over the draft law, but worked on a proposal almost by itself. However, this office could not finalise a draft, probably due to some internal disagreements.[20] Meanwhile, the CPB was formally ratified by the Parliament in August 2003. Subsequently, the President issued a new policy rule according to which the office of the secretariat of the NBC was to be transferred to the DoE, because of the DoE's previous engagements in the negotiations of the Convention on Biological Diversity (CBD).

Several reactions emerged in response to that decision, especially amongst the biotech research institutes of the MoS, MoA and MoH. Those Ministries asked the President to pay more attention to the work that had been done in the former office of the secretariat at the MoS. After publishing and exchanging several letters from both sides, i.e. the Ministries and the DoE, the President finally changed the office again from the DoE to the MoS in a new order on 20 November 2003.

In an important event, the biotech research centre of the MoA (ABRII)[21] announced the successful field test of a variety of GM rice in 2004. This specific rice had shown high resistance to attacks by insects through inserting a Bt gene that produces a toxin.[22] The First Deputy President joined the ceremony of harvesting this first Iranian GM rice in September 2004. He further promised that Iran would start commercial cultivation of this product in the following year. Those events occurred at a time when there was neither a biosafety law nor any regulation with respect to biotechnological products.

[20] Ibid
[21] Agricultural Biotechnology Research Institute of Iran
[22] http://www.scidev.net/en/news/iranian-scientists-produce-countrys-first-gm-rice.html

The DoE contended shortly after that tests on the health and environmental risks of this product had been insufficient and that the crop might incur substantial problems. The head of the DoE asked the MoA to stop cultivating this crop and to undertake adequate safety studies. She asked for satisfactory scientific evidence showing this product was safe.[23] The head of the ABRII reacted vigorously, condemning the DoE for having insufficient knowledge of biotechnology and biosafety. He attested that the safety assessment of the product had been done and there was no basis for more concerns.[24]

At that time, the DoE prepared a draft rule to ban cultivation and production of any GM crops before finalising the biosafety law. The reactions of experts and the MoA again posed a barrier to approving this rule by the Cabinet. Eventually, due to the pressures of the DoE and some inter-Ministerial conflicts, the MoS sent a letter in early 2005 to the President stating that this Ministry was not able to keep administrating the office of the secretariat. The sequence of events and disputes urged the Cabinet to make another decision in July 2005 specifying the new location of the office of the secretariat to be the MoA. This stipulation also asked the members of the NBC to finalise the draft of the law within three months.

In September 2005, Mr Ahmadi Nejad replaced President Khatami. Consequently, he changed the Ministers and other medium-level offices. In February 2006, the Cabinet decided to change the location of the office of the secretariat back to the DoE, presumably after an agreement between the Minister of Agriculture and the head of the DoE. Subsequently, the DoE asked other Ministries to take part in negotiating the draft biosafety law.

2.6.2. Second period of Negotiations over the Draft after 2006

The second period of negotiations, from April 2006 until the approval of the law in May 2009, can be divided into three main stages within which the Ministries and organisations discussed the draft law. The first stage was from April to December 2006, when senior representatives of some Ministries invited by the office (including the MoA, MoS and

[23] "Dam va Kesht va Sanat", volume 57, September 2004, p. 18-20.
[24] Ibid, p. 21-23.

MoH, for which their senior representatives were biotechnological experts), as well as the head of the office who was also the senior representative of the DoE, gathered to finalise a draft. These sessions were called the Coordinating Committee sessions. After ten sessions, followed by a two-day gathering, they could not reach a consensus on many aspects of the law. In December 2006, the head of the DoE arranged an NBC session, composed of the First Deputy President and other Ministers, to address the problem. As a consequence of this session, the second phase of legislation started in December 2006 and lasted until May 2007 under the title of the Reviewing Committee, composed of the head of the DoE and the deputy of other Ministries. This Committee eventually developed a draft and passed it to the Cabinet, while some issues regarding the scope of the law remained disputed. The third stage was the Parliamentary discussions in which the involved Ministries and the DoE discussed again the Government's bill, and the result of this round was an entirely different draft in comparison to the original bill. This draft was eventually passed by the Parliament in May 2009 and came into force in August of the same year.

In April 2006, the DoE started the process of preparing a draft biosafety law through inviting the seemingly relevant organisations at that time; these included MoS, MoA, MoH, the Ministry of Industry (MoI), the Ministry of Trade (MoT), the Ministry of Foreign Affairs (MoFA), and the Organisation of Standards.[25] Every department had been asked to send its senior representative responsible for presenting its views of the biosafety law. In response, the MoS, the MoH and the MoA selected a biotechnological expert from their biotech research centres. For the other Ministries and organisations, only the representative of the MoFA was to some extent familiar with biotechnology and biosafety, while others did not engage in the process seriously.[26] Even the head of the office of the secretariat, located in the DoE and representing the views of this department, was not a biotechnology expert but an expert in nanotechnology.

Disagreements about different parts of the law came to the fore shortly after holding the first two sessions, at which participants put forward their opinions about characteristics

[25] However, those other Ministries and organisations left the process of negotiation after the NBC session and did not take part in the second and third round of negotiations.
[26] Both the representatives of the MoI and MoT mentioned in interviews that they had participated in the sessions just to be informed about the law. The Organisation of Standards also did not participate in most of the sessions.

of the biosafety law. Disputes tended to emerge between the DoE on one hand and the MoS and the MoH on the other, while the MoA supported the DoE on some issues, backed the MoS and the MoH on others, and in some respects had its own approach.

After ten sessions discussing the biosafety law, followed by an unsuccessful two-day gathering, the head of the DoE arranged an NBC session to resolve the controversies through leveraging the political authority of the First Deputy President and other Ministers. However, her expectations were shattered by the serious disputes that emerged in that session. Subsequently, the First Deputy President asked the MoH, MoA and MoS as well as the DoE to sit down again to reach an agreement over the draft biosafety law.

In starting the new sessions, called the Reviewing Committee (RC), the head of the DoE asked the deputies of those Ministries, rather than their senior officials, to take part in the sessions. The head of the DoE chaired all the RC sessions. Following eight sessions, a draft biosafety law reached its finalised version. The most explicit disagreement was over the scope of the law in which the MoS was asking for the exemption of both R&D activities and production processes, while the MoA was insisting on having both of them in the scope of the biosafety law. The MoH had no problem with this version as pharmaceuticals were exempted from the law, although the DoE was not happy with that decision. This draft was eventually sent to the NBC and the Cabinet for final approval and then transmission to the Parliament.

As the Parliament normally sends bills to its relevant internal committees for further discussion, in this case it sent the bill to the Agricultural Committee of the Parliament, as the main relevant committee. Subsequently, the Agricultural Committee of the Parliament asked different Ministries, either their senior representatives or their deputies, to take part in the new round of negotiations over biosafety to improve the suggested bill. Therefore, the senior representatives of the MoH, MoA, MoS and DoE in the CC and the Deputy Ministers, as well as the head of the DoE participated in those negotiations. The result of that interactive process was an amended version of the biosafety draft published in October 2008, with substantial alterations from the Government's bill. Considerable

changes in the draft urged the Government to withdraw its proposed bill on 1 January 2009.

The head of the Agricultural Committee of the Parliament announced shortly after that the urgent need for a biosafety law committed the committee to sending its own proposal to the Chamber as the new bill for Iran's biosafety law. Subsequently, the biosafety law was passed by the Parliament in May 2009 with few alterations in comparison to the new bill, and came into force in August 2009.

An interesting point about the three stages of negotiations in the second period of biosafety policy making in Iran, starting in 2006, is that the representatives of the Ministries and organisations in these phases varied. For the first phase, the CC was almost entirely composed of biotechnological experts as the senior representatives of Ministries and organisations. For the second phase, the RC sessions were held by inviting the Deputy Ministers rather than the biotech experts, and for the third phase, both experts and deputies participated in the sessions of the Agricultural Committee of the Parliament. Intriguingly, the controversies persisted in all three phases, while the outputs of those phases were three different results: nothing from the CC, a draft from the RC and an entirely different draft from the Parliamentary discussions, from which developed the biosafety law of the country.

2.7. Overall Characteristics of the case of Iran

The case of biosafety regulation in Iran represents several characteristics that deserve to be studied. This experience is ultimately characterised by the high degree of controversy among the Governmental organisations, chief among them the DoE, the MoA, MoS and MoS, and by the absence of any public dispute, media coverage, considerable international pressure or private benefit-seeking companies. However, in the context of Iran the three Ministries are responsible for developing biotechnology in their research centres, while at the same time the MoH is responsible for the health of the population and the MoA is responsible for ensuring there is enough food for the people.

On this basis, one might expect the MoA, as an organisation responsible for both developing agricultural science and feeding the population, to adopt a promotional approach in defending the development of GM crops, and the MoH, as an organisation which is in charge of ensuring human health, to take the side of caution. Ironically, the positions were reversed as the MoA has taken a cautionary approach while the MoH has chosen a promotional perspective. Hence, this situation was not a simple case of conflicting responsibilities, and if it was such a problem, the involvement of either the First Deputy President at the NBC, the Cabinet after that, or the passage of the law by the Parliament should have resolved the issue. However, none of these political interventions could achieve a resolution either throughout the process or after the passage of the law.

In addition, there is another difference between the case of Iran and the experiences of the advanced countries. For Iran, the debates were not around the risk assessment of certain products, but over approving the text of a GM biosafety law.[27] In this sense, the case of biosafety regulation in Iran lies at the heart of two broad and largely separate literatures: regulating technological risk on the one side, and the literature of public policy analysis, focusing on the process of public policy making and Governmental procedures on the other. Therefore, it is not merely a case of adopting a simple framework from either, but there is an intricacy in linking them to each other in a way that could provide a useful theoretical framework. Given this background, in the next chapter I will discuss those relevant theoretical fields that might help in explaining the controversies and changes in the process of biosafety regulation in Iran.

[27] Although there were some disputes in 2005 when the successful development of the GM rice advertised, because the MoA in the new Government banned the cultivation of the GM rice, all debates concentrated on the proper content of the biosafety law that in turn was supposed to inform the general guidelines of the risk assessment and risk management.

Chapter 3. Theoretical Considerations

3.1. Introduction

In this chapter, I will review the relevant literature to extract useful insights for analysing the controversies about the biosafety law in Iran and the policy changes to the drafts suggested for this law. According to the previous chapter, the case of biosafety regulation in Iran could be epitomised by the following three characteristics, each of which having been the topic of different literature streams:

1. It is an example of regulating technological risk, as the general concern of biosafety is regulating the possible risks of biotechnological products in conditions of scientific uncertainty and international policy differences and conflicts.
2. It is marked by a high degree of controversy between Governmental organisations, which has lasted several years, and might continue.
3. There were three substantially different policy drafts as the outputs of three rounds of negotiations that constituted the policy changes.

There are considerable bodies of literature around each of these topics that I will review in this chapter illuminating parts of them and their possible application to the case of Iran. The first characteristic is mainly related to the literature on regulation of technological risk that analyses the experience of different countries and the models they have used for regulating the risk by deploying science as a traditional fact-finding entity. The second and the third characteristics of the experience of biosafety regulation in Iran fall within the border of public policy literature in which there are substantial works and contributions on understanding policy processes, policy changes and controversies.

3.2. Regulation of Technological Risk

Confronting technological risks, or avoiding them, has become a central theme of policy in the current era as the population is facing a variety of risks day to day. Therefore, a primary challenge for both the public and the policy makers is finding credible ways of dealing with technological risks (Jasanoff 1986). On this basis, several theoretical and

empirical studies have been undertaken over the last three decades to provide better understanding of the nature of this activity as well as developing better suggestions for policy makers.

An important characteristic of this literature is that scholars have mostly discussed the controversies and differences amongst industrialised countries, in order to find out what factors led to the current regulatory differences (eg Jasanoff 2005, Isaac 2002, Millstone et al 2004), partly because of the importance of the differences and disputes between the USA and the EU over the trade of GM products (Sheingate 2006). With few exceptions (e.g. Murphy and Levidow 2006), this literature has not discussed policy changes as much as it has explained policy controversies. In this sense, one concern of the following literature review is how it might be possible to apply the insights of those studies about controversies among jurisdictions to the case of Governmental controversies in Iran.

However, before discussing those models, I will illustrate the conceptual developments regarding the concept of risk itself as a background picture for elaborating the models of regulating risk. Then I will classify the models of regulation and elaborate on their characteristics and evolution through time, and will discuss their possible contribution to analysing the case of Iran.

3.2.1. Conceptual developments of the concept of Risk

In the last century, Frank Knight (1921) and John Maynard Keynes (1921) were two famous scholars who paid attention to the notions of risk and uncertainty. Distinguishing between risk and uncertainty in the decision-making process was a major progression in economic thinking accomplished by Knight (1921).[28] According to Knight, risk is measurable, while uncertainty refers to the situations in which it is not possible to measure risks because there is no adequate basis for reliable calculation. Therefore, Knight suggested a separation of those immeasurable uncertainties from measurable risks (Knight 1921).

[28] A full and interesting account of the historical development of the notions of risk and uncertainty in the 20th century is provided by Bernstein (1996).

Nevertheless, risk studies were not considered as an important area until the late 1980s and the beginning of the 1990s. Löfstedt and Frewer, in their edition that collects some influential studies about risk, noted: "it is a research area that has grown very rapidly over the last seven years … since then, three new major risk journals … have been launched, and various organizations … have been established." (Löfstedt and Frewer 1998 p. x)

The revival of considering risk as a central topic by policy makers, the public and academia at the end of the 20th century was associated with a shift in conceptualisation of risk. Stirling highlighted this movement by pointing out that the traditional perspectives were based on a variety of instrumental approaches to decision making under uncertainty and held in common a quantitative reductive approach to risk as a function of 'magnitudes' and 'likelihoods' of a determined range of outcomes (Stirling 1998). In contrast, a broader-based, qualitative and descriptive social scientific idea proliferated at the end of the 20th century to emphasise more interpretative and subjective aspects of risk and uncertainty. The consequence of this shift was the change of the focal points away from 'estimation' and 'analysis' to 'communication' and 'management'. In the next section, I will review the evolution of the models of risk regulation in more detail.

3.2.2. Conceptual developments of the models for regulating risk

Governmental and scholarly models for risk regulation have evolved through time. A way of classifying the models of regulation and decision making and their evolution is to consider two different sets of activities: 1) determining the policy goals and ends, and 2) determining the ways of implementing those goals, and which body is more appropriate to perform those activities, i.e. politics or science.

The process of negotiations for drafting the biosafety law in Iran was composed of three rather different stages. In the first stage, biotechnology experts and officials, as senior representatives of Ministries and organisations, gathered to agree a draft, but they couldn't reach a consensus so there was no clear output. In the second stage, only politicians (deputies of Ministries as well as the head of the DoE) joined the negotiations and finally developed a draft biosafety bill. In the third stage of Parliamentary negotiations, both politicians and experts discussed the proposed Government biosafety bill and eventually

developed a rather different output in comparison to the output of the second stage. Those changes in the structure and composition of the bodies (i.e. experts, politicians, or both, albeit from the same Ministries and organisations) participating in drafting the law might imply switching between different models of decision making, so I will discuss those models and their implications for analysing the controversies below.

Considering the classifications of policy goals and policy means, it is possible to envisage the process of finalising a draft biosafety law in Iran as a process of drafting some general policies (such as general approaches to biosafety regulation) as well as the structure of biosafety regulation, including who should decide policy goals in the future and how (e.g. the National Biosafety Committee (NBC) or Ministries), and who should implement those goals and how (e.g. who should conduct risk assessments, risk management, prosecution and enforcement of the law). In other words, the case of Iran was an experience of a policy design aimed to identify some general approaches to biosafety, as well as identifying the proper model of decision making to specify who should define the biosafety goals and how, and who should implement and enforce the biosafety law and how. The following models may also be useful to identify the perspectives of protagonists over the structure of defining policy goals and means highlighted above.

In the following sections, I will discuss the evolution of the models over time along with their possible contributions to characterising the case of Iran and explaining the controversies.[29]

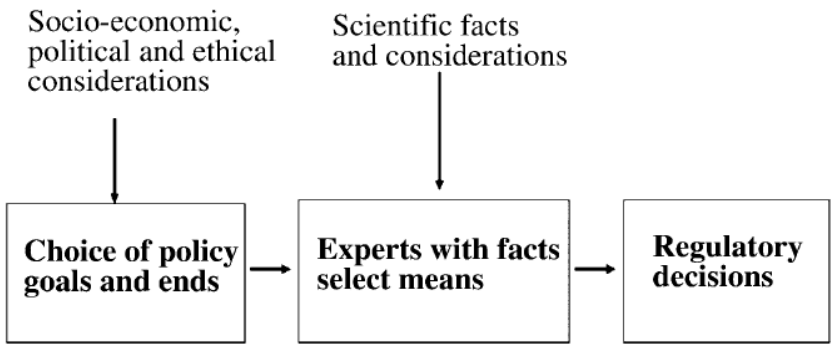
3.2.2.1. Decisionism

In the late 19th and early 20th centuries, the Weberian view of policy making portrayed it as a double stage process in which policy makers firstly define a set of goals and ends, followed by the second stage in which experts or bureaucrats identify the best ways of achieving those goals (Weber 1946). Major elements of this view were also present in the ideas behind the early development of the public policy analysis school when Lasswell (1951) introduced the policy sciences as a set of social sciences that could contribute to

[29] A fuller representation of the historical changes and evolutions of those models can be found in Van Zwanenberg and Millstone 2005

decision making by identifying the best ways of achieving goals. This is what Millstone called a 'decisionist' model of policy making, according to which policy makers decide over 'ends' and the experts suggest the 'means' of achieving those ends (Millstone 2007). A graphical representation of this model is shown in Figure 3-1.

Figure 3- 1 The Weberian decisionist model: politicians choose goals, experts determine means



Source: Millstone 2007, p. 486

A prime assumption of this model is that the sociological context does not impinge on the professional activities of experts in determining the facts, while the choice of policy goals is supposed to be highly affected by such a context. However, this model has not often been applied to the context of risk regulation and analysing policy controversies, in which experts and scientists are supposed to determine the risks of new technological products, or perhaps the risks of the processes of producing those products, because the concerns over risk arose in the 1980s, at which point the decisionist model was replaced by the new technocratic model.

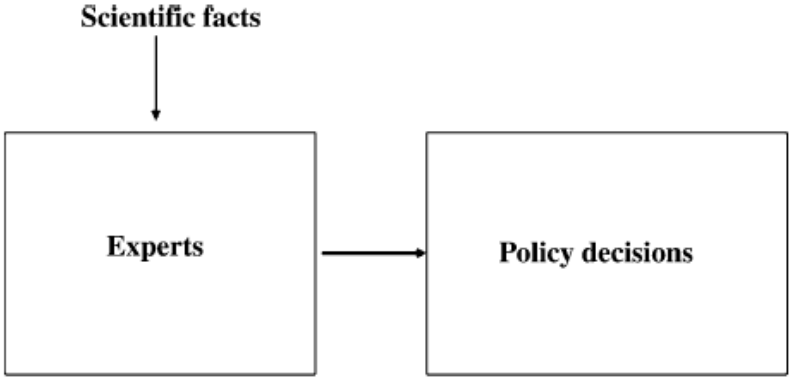
In terms of the policy process in the case of Iran, a Weberian decisionist model might partly characterise the second stage of negotiations in which the politicians (i.e. the head of the DoE and the Deputy Ministers) were supposed to draft the biosafety law, including general biosafety approaches, and the ways of deciding on policy goals and policy implementation in the future. But it cannot characterise this stage completely because decisionism considers experts as those with the responsibility of selecting the means, while in the second stage of negotiations there was no such role perceived for experts.

In this model, controversies are likely to arise due to conflicts between different groups of politicians, as science is often assumed to be objective and neutral. Nevertheless, this model of decision making might represent the views of some protagonists in Iran regarding the best structure for biosafety regulation.

3.2.2.2. Technocracy

The dominant European and the US model in the middle of the 20th century portrayed science as the key element of decision making, or what was called the 'technocratic' model in which science and only science should decide policies and the best ways of implementing them. The technocratic model contains a couple of important assumptions. Firstly, similar to the decisionist model, scientific judgments are seen as unbiased and the relevant scientists are seen as identifying and determining policies neutrally; secondly, there is the idea that science can provide answers to all questions of policy making and therefore there is no need to consider other factors. The application of this model to the context of risk regulation implies that scientists will identify the risks and the best ways of addressing them. A simple model of technocracy is shown in Figure 3-2.

Figure 3- 2 Technocracy: Science and only science determines policy (ends and means)



Source: Millstone 2007, p. 488

In studies about disputes, technocracy simply suggests that one group is entirely correct and the opposition has deviated from the truth, perhaps because of some social factors like lack of sufficient knowledge, or prejudice (Martin 1988). This model has also been applied to analyse policy controversies (Miller 1997). Based on his experiences as a biotechnological expert, Miller argues that there are two sides to the controversies, the

right side, composed of biotechnologists and the wrong side constituting regulators and others. He claims that: "the wrong side of this issue have ignored scientific consensus and allowed – even encouraged – myths about biotechnology to be perpetuated. This raises the question, if reason and search for truth are not the basis for crafting … policy, what is? The answer currently seems to be politics, ideology and self interest." (Miller 1997, Preface of the book, not paginated) Therefore, for technocracy the analysis is simple: one group upholds the spirit of science and is right, and other groups fall under non-scientific norms, like self-interest, prejudice, and ideology.

Regarding the case of Iran, the first stage of negotiations, composed of biotech experts and some officials, to draft the biosafety law could be seen a type of semi-technocratic decision making (but not entirely technocratic, as some other officials were involved too) to determine necessary goals and means of biosafety regulation and the structure of regulation that should set goals and implement the law in future. Nonetheless, a technocratic model might also be an alternative way of characterising the views of some Ministries and organisations about the best ways of structuring biosafety regulation in Iran.

3.2.2.3. Inverted Decisionist Model

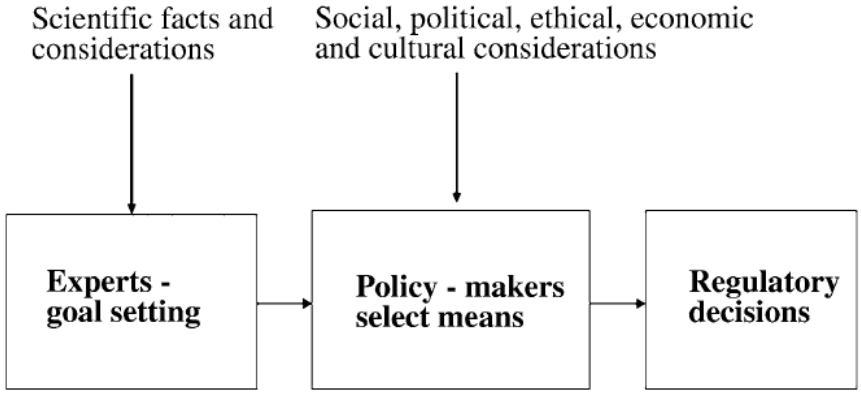
In the context of the USA, technocracy lost its legitimacy a few decades sooner than in the European context, as technocracy was alive in the latter until the BSE crisis in the UK in 1996. In the context of the USA, technocracy was replaced in the 1980s by a new model called 'inverted decisionism' (Van Zwanenberg and Millstone 2005).

The plural culture of USA policy making, within which courts and Congress contribute to decision making, undermined the plausibility of technocracy. In 1958, Congress passed legislation to set out how incomplete and uncertain scientific evidence about cancer risks should be interpreted by Government officials (Ibid).

Consequently, a new model of policy making emerged, incorporating both policy makers and experts, but this time as an inversion of Weberian decisionism. According to this model, scientists only determine the thresholds of safety below which no adverse effects

will occur as a type of policy goal. Therefore, the job for policy makers is to ensure that those safety levels are not exceeded by identifying the appropriate policy means for that purpose (Millstone 2007). In this new model, science sets the goals and policy determines the means, as is shown in Figure 3-3. Similar to the decisionist model, the inverted decisionism model also shares the view that scientific judgments are neutral, although science alone is not seen as sufficient for decision making.

Figure 3- 3 Inverted Decisionist Model. Science defines goals, policy selects means



Source: Millstone 2007, p. 492

In the academic circles, Weinberg articulated a critical paper introducing the concept of trans-science, indicating that "questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science." (Weinberg 1972 p. 209) He gives some examples of questions which could be formulated in the language of science, but which science itself is not able to answer through sound scientific methods. In the context of risk studies, other scholars have warned about the insufficiency of science in providing satisfactory answers to the questions of risk policy making and providing a sound foundation for risk regulation (e.g. Jacobson 1972, Verrett and Carper 1974).

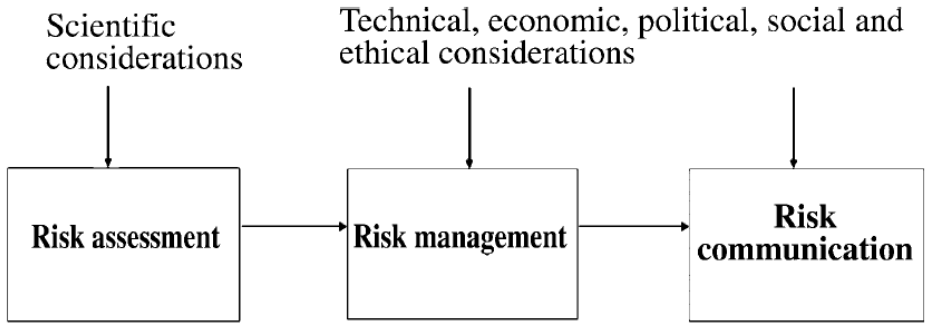
Regarding the case of Iran, it seems that inverted decisionism cannot provide an account for any stages of the negotiations by placing scientists and experts as goal setters, and politicians as the bodies identifying the means. Nevertheless, this model might represent the views of some antagonists in the case of Iran.

3.2.2.4. Towards Risk Assessment and Risk Management: Red-Book Model

A controversial court decision about the threshold of risks and safety in 1980, the Benzene Decision Case, led to the popularity of the concepts of risk assessment and risk management. In that year, the US Supreme Court overruled the decision of the Occupational Safety and Health Administration (OSHA) about lowering the threshold of safety for permitted airborne concentrations of benzene from 10 parts per million (ppm) to 1 ppm (which was the lowest measurable threshold at that time). OSHA made that decision following evidence suggesting that occupational exposure to benzene was linked to rates of leukaemia. The court ruled that OSHA's decision was not legitimate because it did not undertake sufficient scientific risk assessment to justify that there would be significant risk above that level.

In 1983, the US National Research Council (NRC) published an influential book named *Risk Assessment in the Federal Government: Managing the Process* (NRC 1983), which suggests a two-stage model of risk regulation, the first stage being risk assessment, followed by the second stage of risk management. This model is known as the Red-Book Model and is shown in Figure 3-4.[30] According to this model, scientists should estimate risks based on scientific considerations and must be entirely separate from policy makers, who should select the necessary measures to manage those identified risks in order to make sure no risks beyond those thresholds will arise.

Figure 3- 4 Red-Book Model of Risk Assessment and Risk Management



Source: Millstone 2007, p. 495

[30] Because the cover of the report was red.

This model of risk assessment and risk management portrays controversies about the proper threshold of risks as entirely scientific debates, while the differences between countries should be linked to their different ways of risk management. For instance, Jasanoff investigates the differences between risk management experiences in certain countries to conclude that they had different political processes and institutional designs that in turn led to "widely divergent policies for managing the same technological hazards." (Jasanoff 1986 p. 79)[31]

Although this model is not relevant to the case of biosafety regulation in Iran, as the case of Iran was not a case of controversies about assessing and managing risks, different types of this model have largely been applied in several industrialised countries in order to assess and manage the risks of GM products. Subsequently, many studies and investigations have started to examine the performance of this model in practice, especially studies carried out by the scholars of the Sociology of Scientific Knowledge (SSK), which largely concern the assumption of this model that scientific judgments are neutral.

3.2.2.5. Towards a Co-Evolutionary Model

The Red-Book Model faced serious criticism supported by empirical studies showing that scientific advice is often impregnated with the values and interests of scientists and their institutions as well as those of powerful non-scientific institutions (e.g. Jasanoff 1990). The SSK studies criticised the procedures of risk assessment and risk management, which were routinely represented as purely scientific, and illuminated the unrealistic characteristics of the assumption that risk assessments are impartial.

However, those concerns over the neutrality of science, especially in the context of policy making, were present even before introduction of the Red-Book Model. For instance, some studies have suggested that the problem of risk policy making is not just about the uncertainties of scientific assessments, but also about the incorporation of the political, economic and social interests of scientists in definition of the risks, questions to be

[31] Although in her book, she criticises the assumption of the neutrality of scientific advice. I will turn to this issue in the discussion of the next model.

addressed, and so on (e.g. Nelkin 1979, Gillespie et al 1979, Castleman and Ziem 1998). Another study has claimed that the Food and Drug Administration (FDA) of the USA's proposal to ban artificial sweeteners was based on deliberately invalidated data (Havender 1982).

There is a valuable contribution by Wynne (1975) regarding the experience of technology assessment, which was valued increasingly in that time as a vital activity for technology decision making. Wynne points to the problem of mainstream views of technology assessment (not just of risk technologies), which portray scientific knowledge as if it were able to assess technologies neutrally.

Wynne applies those views in his inquiry into the Windscale nuclear controversy in the UK. As a pioneer study, and by portraying the picture of conflicts between pro-nuclear views on the one hand and its opponents on the other, Wynne argues that even scientific judgments should be seen as affected by a broader socio-political context (Wynne 1982). He discusses the two views, which he calls "the views on knowledge and values in politics".[32] The first view is that of 'rational individualism', which considers people as holding clear and stable values and goals, and that their behaviour is organised to achieve these goals. In the second view, which Wynne supports, these values and goals are often considered as vague, unstable and open to persuasion.

Jasanoff, in her book *The Fifth Branch* (Jasanoff 1990), discusses the role of science in policy to bring about a more realistic picture of the interaction between the two. She argues that in practice, the technocratic way of representing policy making does not represent reality, at least in the three cases discussed in her book, because what experts do is "a hybrid activity that combines elements of scientific evidence and reasoning with large doses of social and political judgment." (Jasanoff 1990 p. 229) She implies that regulatory bodies should acknowledge the fact that science and expertise is circumscribed by particular scientific, legal, administrative, and political factors.

In the 1990s, several scholars applied the insights that science might not operate free from biases to analyse the experience of risk assessment and risk management in the

[32] He refers these two views to Unger's book, *Knowledge and Politics* (1975)

context of the USA and the EU (Abraham 1993, Huff 2002). For instance, Abraham discussed how risk assessment of the medical drug 'benoxaprofen' in the UK and the USA may have been biased (Abraham 1993) and Huff tried to show how the monographs of International Agency for Research on Cancer (IARC), which was firstly distributed in 1972, started to deviate from its original neutrality under the influence of industry since 1995.

Wynne, in referring to some crucial, but often overlooked, insights of his previous Windscale inquiry (Wynne 1982) points out that official experts frame risks based on some prior socio-institutional assumptions. He furthers this argument by making a distinction between two types of social framing assumptions that affect judgments: firstly, assumptions about relevant social behaviour, which is the source of differences in scientific reports – such as presuming the same qualities for social organisations in the future – and secondly, framing of what is meant by risk for the purposes of social decision making (Wynne 1992).

Subsequent studies of regulating risk apply the idea of framing assumptions that frame the views of the experts, protagonists or policy makers at different levels. Studies of biotechnology risk regulation mainly use the notion of framing at a country level to analyse the disputes and differences between countries (e.g. Jasanoff 1995, 2005). In an analysis of the debates about biotechnology across the EU, Berkhout (2002) tried to show how arguments about the impacts of biotechnology had been framed differently. Levidow et al point to the issues of framing in the context of European Regulatory disputes over Herbicide Tolerant crops (Levidow et al 1997), and extend those ideas in analysing US-EU conflicts (Murphy and Levidow 2006) and the GM food trial policy within Europe (Levidow and Carr 2009).[33]

Stirling (2008) through displaying the variety of judgments expressed by experts involved in advising the UK government on regulation of GM technology argued that: "the reason that these kinds of 'sound scientific' procedures can yield such contrasting pictures of risk is that the answers delivered in risk assessment typically depend on the framing of

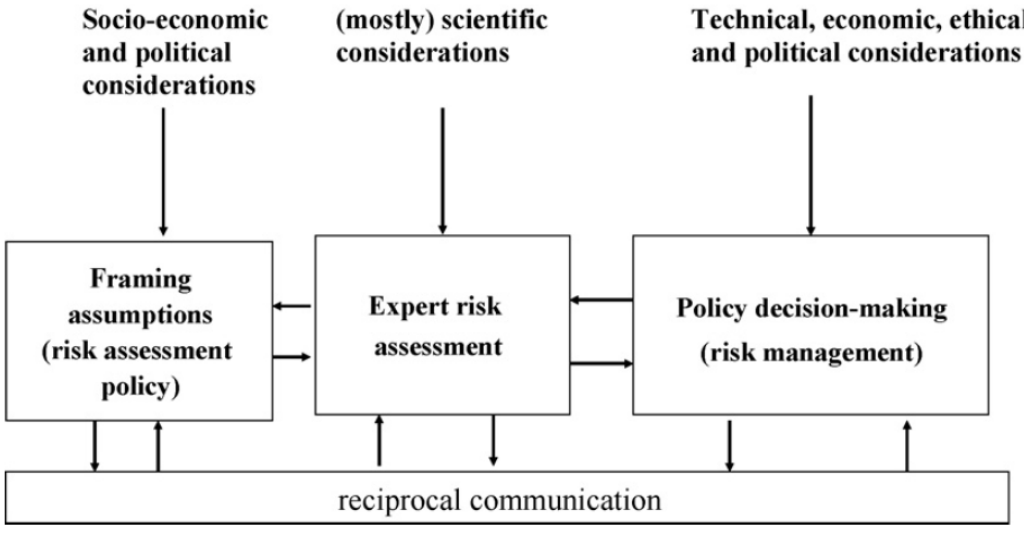
[33] However, as I will discuss in the next chapter, scholars use the framing approach in different ways and I will suggest a workable framework for the case of Iran.

analysis" (Stirling 2008 p. 101). He had discussed earlier that the qualitative framing assumptions would largely influence the perspectives and judgements about risk assessments (Stirling and Mayer 2001).

Different studies conducted by Millstone et al (2004) on understanding the disputes between the USA and the EU over trade of certain technological products and their risks, including GM crops, and later Millstone et al (2008) illustrate the differences between risk assessment experiences of certain countries in the light of their various framing assumptions and the theoretical results of these studies, as well as a categorisation of the possible framing assumptions (Millstone 2009).

Millstone developed a graphical account of a model called a co-evolutionary model of risk regulation which is largely rooted in the insights emerging from the SSK literature (Figure 3-5). According to this model, socio-economic and political considerations affect the experts' risk assessment activities in the form of some upstream framing assumptions. In other words, those framing assumptions are a reflection of socio-economic and political considerations.

Figure 3- 5 Co-evolutionary model: reciprocal links between science and policy



Source: Millstone 2009, p. 628

Millstone proposes that this conception of the framing assumption is very close to the provisions of the Codex Alimentarius Commission in defining 'Risk Assessment Policies'

as policies that should be defined as clearly as possible by risk managers (as a step in risk management), and in interaction with risk assessors and all other interested parties in advance of the risk assessment (Codex 2003). Therefore, this model acknowledges the interactions, or reciprocal linkages, between policy makers and experts, rather than adopting a linear and one-way model of regulation. In this sense, it could represent the third, and partly the first, stages of negotiations in Iran in which both experts and policy makers interacted to develop a draft biosafety law. Nevertheless, this model may represent the views of some protagonists in Iran about the proper way of organizing Biosafety policy making.

Millstone argues that a co-evolutionary view may provide a suitable theoretical tool for investigating the source of differences between risk assessment experiences of jurisdictions by considering their different framing assumptions (Millstone 2009). Millstone et al apply this model to the case of differences and disputes between several countries, and identify several framing assumptions that were shared differently between jurisdictions (Millstone et al 2004, 2008).[34]

However, it should be noted that the case of Iran was not one of risk assessment and risk management, but a process of negotiations for drafting a biosafety law in three different phases, almost always composed from the same organisations (i.e. the DoE, MoA, MoH and MoS), but at each stage with a different output. Therefore, I might consider a model in which experts and policy makers of the relevant organisations are assumed to be circumscribed by some socio-political factors that might lead to different and contrasting framing assumptions.[35]

In this sense, it may be possible to envisage the case of biosafety policy making in Iran as an experience of risk policy making that might be affected by some prior framing assumptions, which normally come from the socio-political context, and the differences between those assumptions might provide an explanatory account for the controversies between those organisations.

[34] I will discuss the detail of different types of framing assumption in the next chapter in order to develop my theoretical framework. However, this chapter discusses the theories in a more general level.

[35] There are many philosophical and sociological schools asserting the partiality of knowledge and science, but each based on their specific perspectives. I will not go throughout those debates, but also I will not accept the strong approaches suggesting that human knowledge and science are entirely constructed (eg Barnes 1974, Bloor 1976) and therefore there would be an absolute relativism.

Nonetheless, there are some concerns about this idea. Firstly, the concept of framing assumptions has been used for scientific risk assessments and therefore there is a concern about whether or not it could be applied to the case of legislation. The second concern is whether or not the concept of framing assumptions, which has been largely applied to country-level studies, could be used for analysing the differences and controversies between organisations and Ministries within a country. I will go on to discuss the literature on public policy analysis and studies on controversies between Governmental departments that might contribute to addressing the above concerns and may providing additional insights.

Before discussing that literature, as I mentioned that those models also could represent the views of protagonists about the proper ways of structuring biosafety in Iran, and as those models are based on some assumptions that might account for the controversies, I will summarise them according to two basic assumptions that might provide a further theoretical tool for this research.

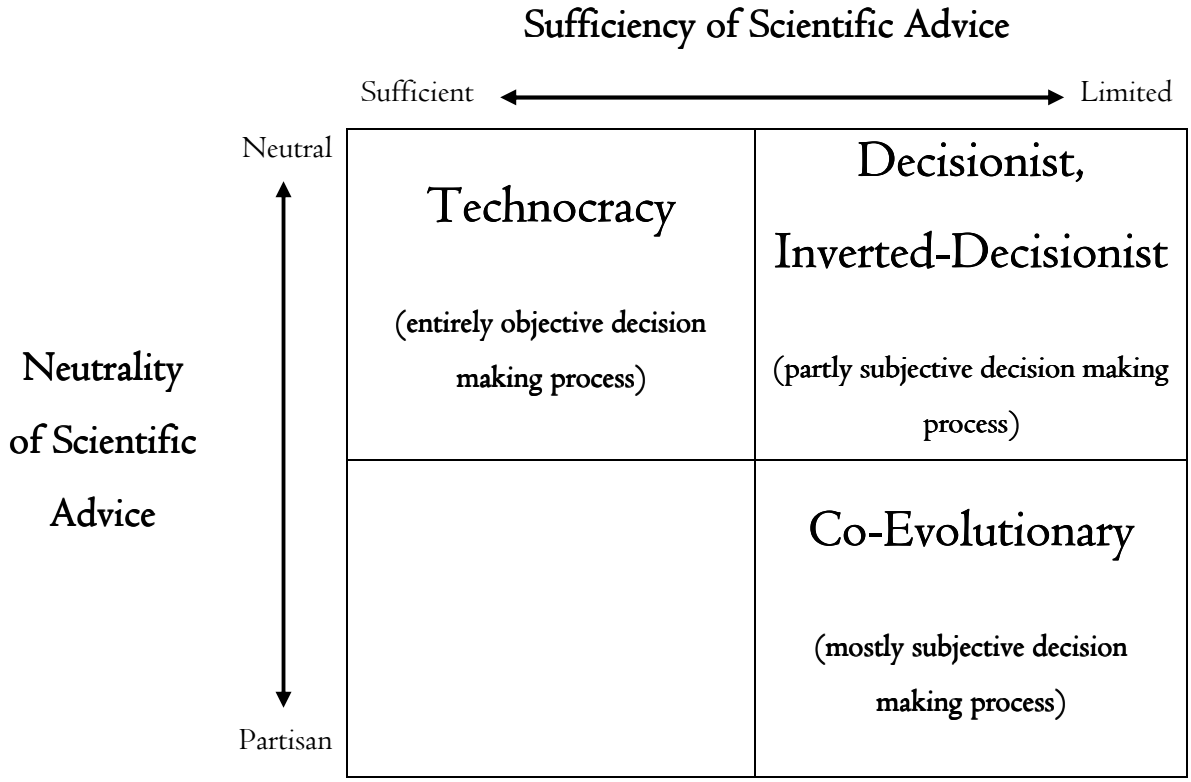
3.2.3. Summarising the models of regulating risk

The four presented models of the regulation of risk could be characterised by their two principal assumptions: one about the impartiality of scientific judgment, and the other about the sufficiency of science in answering relevant policy questions. The first characteristic as is shown by the vertical axis in Figure 3-6 includes two views about scientific advice as entirely neutral (at the top) or as partisan (below). The second feature is represented by the horizontal line and covers two views of scientific knowledge: the view suggesting that science is sufficient for answering all relevant policy problems on the left, and the alternative that considers a limited ability for science in this sense on the right.

Thereby, technocracy is the view that not only considers scientific activities as neutral, but also assumes that science is able to answer all policy questions, which in turn renders the decision-making process entirely objective. Both decisionist and inverted decisionist models share a similar idea to technocracy in terms of the neutrality of science, but they do not perceive science as a sufficient source for answering all relevant policy questions.

Therefore, they consider a pivotal role for policy-makers in the decision-making process alongside science. Finally, the co-evolutionary model rejects both characteristics of the technocratic model by not only questioning the sufficiency of science for answering policy questions, but also by arguing that scientific activities are not always neutral.

Figure 3- 6 summarising the models of risk regulation according to their assumptions



As I stated before, the case of Iran involved a set of negotiations about the goals of biosafety and the means of achieving those goals through identifying the proper procedures of risk assessment and risk management and the roles and responsibilities of different organisations. Hence, the above assumptions about the neutrality of science and its sufficiency for policy making might have been present in the views of protagonists in the biosafety system in Iran, and I will use them in my theoretical framework, which I will elaborate in Chapter 4. Now, I turn to the literature of public policy analysis to investigate the possible contributions of this literature either in explaining policy controversies or policy changes.

3.3. Public Policy Analysis

The literature stream of public policy analysis emerged mainly after the Second World War, starting with the seminal work of Lasswell (1951), which introduced policy science as a new discipline focusing on the application of the social sciences to the issues of governance and government, and to provide a greater assurance that policies will achieve their goals. As Allison pointed out, Lasswell's work was part of the public administration school, focusing on the means of achieving chosen ends by politicians (Allison 2006). In this sense, the ideas of Lasswell (1951) could be traced back to Weber's ideas on policy making which included the decisionist model discussed in the previous section, according to which, policy chooses the goals and science determines the means.

Public policy benefited much from governmental support in the 1960s (Deleon 2006) especially due to the popularity of technocratic models in that decade (Allison 2006), according to which science is privileged as a source that could identify alternative goals and their outcomes as well as the means of achieving these goals (Fischer 2007). Scholars of public policy analysis continued to consider ways of formulating policy goals and determining policy means, as well as the implementation processes, among topics of analysis, even after technocracy lost its credibility. In this way, several approaches have been introduced by scholars to analyse various aspects of public policy making (e.g. Hill 2008, Sabatier 1999, 2007, John 1998).[36] These approaches imply different analytical tools for investigating different aspects of policy making experiences such as policy processes, policy varieties, policy changes or policy controversies.[37]

In this section, I will briefly discuss the approaches applied for analysing policy controversies and policy changes as the two aspects of biosafety policy making in the case of Iran, both of them mainly concerned with the process of policy making rather than policy implementation.

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[36] A recent and fuller account of the history and topics of public policy analysis is brought together in the Oxford Handbook of Public Policy by Moran et al 2006

[37] For instance, Hill (2009) distinguishes four main approaches to analysing the policy process, as follows: 1- theories of power, 2- networks, 3- institutional theory and 4- rational choice theory. In a different approach Sabatier (1999 and 2007) considers some synthesised frameworks for explaining policy processes: the policy advocacy coalition (Sabatier 1991 and Sabatier and Jenkins-Smith 1993), the policy streams approach (Kingdon 1984, 1995), and the punctuated equilibrium model (Baumgartner and Jones 1993).

3.3.1. Approaches to analysing policy controversies

In their seminal work on analysing policy controversies and looking for ways of resolving them in practice, which built on case studies of controversies between Governmental agencies and organisations in the US and Germany, Schon and Rein (1994) characterise policy controversies as predicaments in which 1) the protagonists emphasise and refer to different facts in their arguments regarding the relevant evidence, and 2) even if they employ or discuss a similar fact, they give it different interpretations. This definition is quite close to the observation of Wynne (1982) of controversies as situations in which protagonists interpret the same reality in different manners.

Schon and Rein (1994) count three contrasting views in public policy analysis that have been applied and might contribute to a better understanding of policy controversies. They count the first approach as the 'policy sciences' approach. This view shares similar fundamental assumptions with classical economic views in which decision making is conceived as a problem of selection among well-known options (i.e. presuming the alternatives and their possible consequences are well-determined). In this view, if a dispute arises, the policy sciences could provide value-free analyses to find the right answer.

Schon and Rein (1994) argue that this approach cannot account for the types of controversies defined above, because it presumes policy sciences are a means to find the right answer to debated issues and therefore there will be no controversy after the involvement of science. Moreover, as I discussed earlier in this chapter, this view of the neutrality of scientific judgments and their sufficiency to answer policy problems resembles a technocratic view of policy making that has been widely criticised in the SSK literature.

In the second approach, which is a type of 'Rational-Choice' theory (John 1998), policy making is conceived as the process of contention between interest groups, each of them holding different objective interests (Trueman 1962) and formulating different strategies for achieving their goals (Coleman 1982). This model does not scrutinise the role of scientific advice in decision making; however it is close to either the decisionist or inverted-decisionist model of policy making in which politicians are circumscribed by a

socio-cultural context and thus each of them will adhere to their own objective interests and leverage different means for realising their intentions. Therefore, the controversies in this approach are perceived as conflicts between objective interests.

Although this approach might work in some situations, Schon and Rein (1994) argue that it cannot explain the endemic character of controversies, particularly those controversies that last for several years. This is mainly because conflicts of interests can normally be resolved through the process of negotiation, bargaining and compromise of interests in a known socio-political structure. Considering the case of Iran as a process of several years of unresolved controversies and many sessions of negotiation over the content of the draft biosafety law, this approach seems to offer a limited applicability.

However, there are more theoretical concerns with this approach, regarding its emphasis on the objectivity of interests and the importance of instrumental rationality, which make it more vulnerable as a basic framework of study. Schon and Rein (1994) criticise this approach for its assumption that the interests of antagonists are objective and given in a well-defined situation, when the complexity and possible uncertainty of situations and decision making is a barrier to such objectivity. This is similar to the view of Wynne (1982), who criticizes the views that presume interests are clear, objective and stable, as I discussed in section 3.2.2.5.

Another problem with this approach lies in its assumption that antagonists share a similar and objective definition of the policy problem, whereas in many situations this is not the case (Rittel and Webber 1973). In this sense, turning to the facts might amplify rather than resolve the issue (Schwarz and Thompson 1990).

As an alternative, Schon and Rein propose the 'frame' approach, in which controversies are seen as arising because of conflicts between the frames of the antagonists. Frames, as underlying structure of belief, largely define the interests of protagonists and determine their policy positions and even their understandings of the policy problem. Thus, having two different set of frames could lead to two different understandings of the policy problem and policy interests, which in turn might engender enduring controversies. In other words, a policy controversy is a situation in which "two or more parties contend

with one another over the definition of a problematic policy situation and vie for control of the policy-making process... it is the frames held by the actors that determine what they see as *being* in their interests and, therefore, what interests they perceive as conflicting" (Schon and Rein 1994 p. 28-29) [italics in original].

This is an approach that Fischer calls a post-empiricist (or post-positivist) approach to policy analysis that does not start with an obvious policy problem (Fischer 2003) but by envisaging policy actors in a complex situation with a primary difficulty of making sense of that complexity and the possible uncertainties (Hajer and Laws 2006). In this sense, it is the frame of the protagonists which largely defines their understanding of the situation, of the policy problem and of what is in their interests (Schon and Rein 1994), and which is supposed to provide a satisfactory explanation for the policy controversies (Surel 2000).

In short, two main approaches have been applied to explain political controversies. The first one is 'rational-choice' theory which considers the interests and goals of the protagonists as objective and given and that controversies arise because of conflicts of interests. According to the second approach, controversies emerge due to differences of the frames of the involved groups, which in turn leads to different definitions of the policy problems and even to different understandings of the involved groups' own interests and the interests of each other.

These two views of analysing policy controversies are similar to the two views discussed by Wynne (1982) and represented in the previous section. The primary difference between the two approaches discussed by Wynne is the assumption of objectivity of interests and instrumental rationality which is shared by the first view, while it is criticised in the second approach, which proposes that interests can be vague and subject to persuasion in a complex situation. As I discussed earlier, the SSK literature (e.g. Wynne 1982) has also largely adopted the second approach by considering the effects of the broader socio-political system in the form of some prior framing assumptions.

Hence, the co-evolutionary model I adopted earlier, as potentially the most appropriate model for the experience of regulation in Iran, shares several basic elements with the

framing approach to analysing policy controversies. However, as the concerns of the literature regarding technological risk regulation were the experiences of risk assessment and risk management and the differences between countries on this issue, the concept of framing assumptions has mainly been extended by this literature to analyse the scientific risk assessment debates rather than general policy-making experiences (e.g. Wynne 1992, Jasanoff 1993, Millstone 2009).[38]

In this sense, the theoretical tools of public policy literature on controversy analysis might help to address the concerns over the possibility of applying the framing approach to the controversies over biotechnology regulation in Iran. On one hand, the literature on public policy applies the notion of framing to broader issues of policy making, not just to scientific risk assessments. On the other hand, the framing approach was developed in this literature to be useful in studying the controversies within a jurisdiction.

Therefore, the idea of framing and framing assumptions could well offer a useful theoretical tool for analysing the case of inter-organisational disputes in the system of biosafety policy making in Iran, which on one hand is an experience of risk regulation and on the other hand is an experience of public policy. In the next chapter, I will consider the broader literature, applying both the notions of frames and framing assumption in more detail to develop a theoretical framework for my study.

However, there is another aspect of policy making in the case of Iran that should be considered: three different outputs as the result of three rounds of negotiations. The first round of negotiations was mostly composed of experts and non-expert senior representatives and finished without a formal draft output; the second round was composed of policy makers (i.e. Deputy Ministers and the head of the DoE) and ended with a draft that was entirely changed in the discussions of the Agricultural Committee of the Parliament, composed of both experts and policy makers as well as MPs of the Agricultural Committee of the Parliament. In the next section, I will discuss those approaches for analysing policy changes.

[38] As I will discuss in the next chapter, there are some recent studies analysing biotechnology regulation in general, such as Jasanoff 2005, Murphy and Levidow 2006 and Levidow and Carr 2009, borrowing from the contributions of Shon and Rein and Hajer. However, firstly they just adopted the notions of frame, narrative, and discourse uncritically without discussing the literature on public policy in more detail and secondly they applied those notions for analysing country differences rather than domestic controversies. I will discuss this literature in more detail in the next chapter.

3.3.2. Approaches to analysing policy changes

In studying and analysing public policy, Peter John (1998) counts understanding policy change as a main topic of investigation for students and scholars in this field. He enumerates three approaches that might contribute to explaining policy changes: 'rational-choice' theory, the 'idea-based' view, and 'socio-economic' approaches. According to John, the idea-Based view seems to have a better explanatory power in analysing policy change in comparison to the two other approaches.[39] The definitions of these three approaches, which could be combined to yield hybrid approaches too, are:

- *Rational-choice theory*: the preferences and bargaining of actors and institutions in a determined socio-economic structure explain decisions and outcomes.
- *Idea-based view*: ideas about solutions to policy problems circulate and gain influence independent of or prior to interests in the policy process, and determine the decisions and policy outputs.
- *Socio-economic approaches*: powerful socio-economic forces ensure that the intentions of the most powerful determine the outputs and outcomes.

I discussed rational-choice theory in the previous section, which envisages policy making as a process in which the interests of actors are given in a determined socio-economic structure and the policy outputs emerge in a process of bargaining among these actors. In this way, the policy output will change if the interests of the actors change, even if the socio-economic structure remains unchanged. Referring to the discussions in the previous sections, this approach, which presumes public policy making as a process of conflicts of objective interests, is broadly criticised by the SSK literature, and I will not adopt this view in my theoretical framework.

The socio-economic approach proposes that, because the policy output is determined by the most powerful organisation, changes to the policy output reflect changes in power relations. In this sense, three outputs for three stages of negotiations in the case of Iran could be the result of changes in the dominant power at each stage. This is a hypothesis

[39] He also refers to two other approaches that fit better in explaining policy stability, as opposed to policy change: institutional approaches, and group and network approaches.

that cannot be rejected at this point, although the stability of the office of the secretariat for the NBC, as well as the stable structure of the NBC during the process and that of the involved organisations might raise questions about validity of this proposition.

The idea-based view suggests that policy changes because of changes in the ideas of policy makers or protagonists. In this sense, the output of each stage of negotiations in Iran might have changed because new ideas for resolving the policy problem had emerged. However, a primary issue in the ideas-based approach is defining 'ideas', as this term could be used with several meanings, ranging from ideas about facts and technical knowledge (Sabatier 1998) to worldviews and ideologies (Schon and Rein 1994). As I stated above when defining the controversies, the ideas that might account for the controversies and the change in policy output cannot be reduced to ideas about facts (Hajer and Laws 2006). Therefore, the relevant ideas in this context may resemble general ideas similar to the notion of frames (Keeley and Scoones 2003), and I will use this conception of ideas for the purpose of this study. Thus, this version of the idea-based view would suggest that the policy output may have changed because of changes to the policy frames (Hajer 1995).[40]

Considering the case of radical policy change, there is another proposition in the framing approach suggesting that policy might change because the dominant frame could not resist new, and maybe social, tensions and criticisms that in turn could lead to a change of the dominant frame (Surel 2000).[41] Murphy and Levidow apply this concept by combining it with the Advocacy Coalition Framework of Sabatier and the Policy Discourse Analysis of Hajer to analyse policy shifts in Europe as a result of public contestation attacking the dominant paradigm (Murphy and Levidow 2006). In this sense, the work of Murphy and Levidow suggests a combination of the two previous approaches by considering a dominant and powerful frame which was replaced as a result of criticisms from a rival frame.

In short, the current theories suggest that the policy output of the three stages of negotiations changed, possibly because of a change in the dominant power, possibly

[40] In the next chapter and in developing my framework, I will discuss the different meanings of frame and narrative in more detail.
[41] This approach is quite similar to the elaboration of Kuhn's scientific paradigm shift as the result of new questions and criticisms.

because of a change in the policy frames of the protagonists in the system, leading to new understandings, or possibly because of the raising of new criticisms that in turn could jeopardise the position and power of the previously dominant frame.

Having reviewed the important streams of literature deemed relevant to the case of Iran in the previous sections, it is now possible to redefine the objective of the current research and the research questions in more theoretical language in the following section.

3.4. Refining the research objective and question in theoretical terms

The previous findings of the literature about risk regulation, along with the two streams of public policy literature, can now be used in defining the concerns and objectives of this research in a more theoretical way. To recap the main theoretical points:

- Studies about the disputes over biotechnology regulation suggest that the main root of controversies might be the diversity of the framing assumptions between countries. However, this concept has not been developed for analysing domestic organisational disputes over biotechnology regulation.
- Work on identifying the sources of controversies in public policy decision making, the topics of which have not been risk but other popular types of policy making such as homelessness, suggests that differences in the frames of the protagonists might account for the persistence of controversies.
- The literature on policy change suggests that policies might change as a result of changes to the frames of the protagonists, because of changes in power relations, or as a result of intensive criticisms of the dominant frame.

Refining the research question from this theoretical perspective, the main research problem of this study could be stated as:

Does adopting a co-evolutionary model for policy making help explain the Iranian controversies over biosafety regulation by focusing on contrasting framing assumptions?[42] *Furthermore, is it possible to explain the changes to policy outputs in the light of*

[42] I used the term 'framing assumption' rather than 'frame' in formulating the questions. I will illustrate the reason for preferring framing assumption over frame in the next chapter.

changing framing assumptions, or do other factors like changes in power relations need to be considered to explain the changes in the policy outputs?

Thus, the primary empirical research question is defined as:

- *To what extent did the controversies between the MoS, MoH, MoA and DoE arise from differences in their framing assumptions? And how could these framing assumptions contribute to explaining policy changes?*

This research question could be divided to the following sub-questions:

- What types of different frames or framing assumptions can be identified and elicited from the participatory organisations regarding the system of biosafety regulation of Iran?
- To some extent are they different and even contradictory?
- How did those framing assumptions change over time and why?
- Can the changes in the framing assumptions help explain changes in the policy outputs of each stage?
- If the framing assumptions remained unchanged, is it possible to understand the changes of the output of each policy stage in the light of changes to the dominant power?

Answering these questions needs more clarification regarding the concepts of frames and framing assumptions, as well as a suitable theoretical framework and methodology for data gathering and data analysis. These tasks are the topic of the next chapter, which discusses the overall design of the current research.

Chapter 4. Research Design

4.1. Introduction

In this chapter I will discuss the design of the current research, including the research strategy, theoretical framework, methodology, data sources and so on.

4.2. Definition of Research Design

In the physical sciences and to some extent in psychological research, the term 'research design' normally refers to providing experimental conditions under which the desired variable can be measured and other intervening variables can be controlled. In the supposed conditions, the researcher would then be able to interpret the events and draw causal conclusions (Blaikie 2000). Blaikie also quotes from some psychologists that in their view, research design aims to provide a situation in which individuals can be compared and analysed and an interpretation could be derived, although it might not be possible to reach a unique interpretation (Labovitz and Hagedorn 1976: cited in Blaikie 2000, p. 36).

But research design in other disciplines can be different, as Blaikie points to two other types of research design, in addition to the experimental type mentioned above. They are: 1) linear and very quantitative approaches, and 2) qualitative research that normally uses interrelated processes. He suggests that for many social science researchers, it would be very difficult to run experimental research, as the ability to control the variables is limited. Therefore, while many social scientists prefer to use quantitative approaches, there are still many social scientists who prefer to use the qualitative approach (Blaikie 2000).

My research is a study of a unique set of events in the past that increases the issue of control over variables. Therefore, it is not possible to use experimental approach as a basis of my research design. Moreover, considering the complexity of the case of biosafety regulation in general and contested assumptions and ideas that might lay the controversies within the specific context of Iran, linear and quantitative approach might not also cover several characterizations of the case of biosafety regulation in Iran, especially those

possible framing assumptions. Consequently, I prefer to consider a qualitative approach as the basis of my study focusing on a specific case of biosafety policy-making in Iran.

Blaikie endorses the approach to research design suggested by Yin (1989), in which research design is defined as an action plan for linking research questions, empirical data and research conclusions. In criticising views focusing on specific methods of data gathering instead of on research design, Blaikie suggests an alternative view that introduces eight central elements of research design, considering the first four points as the most important: 1) research topic or problem, 2) research questions and objectives, 3) research strategies, 4) concepts, theories and models, 5) data sources, 6) selection from data sources, 7) data collection and timing, and 8) data reduction and analysis. However, he notes that the order of these eight elements may be different in different research.

My research to a large extent fits the research design model suggested by Blaikie. However, I wish to further clarify my view of research design in more detail, which might also imply differences from Blaikie as follows.

As the previous chapters indicate, I prefer to take a broad view of research design, suggesting that research is a way of linking two separate worlds of theories and concepts on one hand, and reality and experiences on the other, in order to answer a set of reasonable and interesting questions. Therefore, there is a distinction between two separate sets of questions, the empirical questions and the theoretical questions. In this sense, designing research is a way of developing a reasonable means to transform practical problems into the theoretical world, restating them in the language of theories as a window through which to look at the problems, developing a conceptual framework as a toolbox for dealing with the problems (which also guides which data are necessary and how to collect and analyse them in order to find the answers to the theoretical and empirical questions), and finally, through the implications of all these intellectual steps, finding a solution to the practical problem.

If we envisage the process of science policy research, starting from a real problem and ending with a solution, academic research has the task of transforming this problem into the theoretical world, solving it in that world and then retransforming it to the real world

again. In this picture, the role and importance of theories and hypotheses are more than just an element of the research design, but a core element that guides the future steps of the research (this view is very close to Yin 2003b, which I will discuss in the next section and different from Blaikie who counted theories and models as just a building block for research design). Moreover, the theoretical research questions are not something 'out there' to be found prior to the application of theories, but arise as the result of transforming, or linking, real-world problems to the world of theories and concepts, thereby yielding the theoretical research questions.

According to this view, I have therefore taken some key steps of the research design in the two previous chapters, which are: 1) the context of study and the particular empirical problem has been discussed, 2) the body of literature has been reviewed and relevant theoretical considerations have been identified, and 3) the practical question has been restated in the language of theories by concentrating on framing assumptions.

The aim of this chapter is to fulfil the remaining tasks, which are clarifying the concepts of frames and framing assumptions, to develop useful units of analysis; examining their usefulness and applicability in the case of Iran; developing a theoretical framework; and identifying the required data sources and the ways of gathering and analysing these in order to answer the research questions.

4.3. Research Strategy

Methods of data collection on their own do not determine particular aspects of the research, but it is the researcher in interaction with theories and reality who designs the research and identifies the use of the methods. In designing this research, I assume that the current case of Iran could provide sufficient and interesting resources to be combined with the world of theories and contribute, not only to better explain an intricate policy problem, but also to suggest useful insights for resolving the problem as well as contributing to current theoretical debates. In this sense, my research strategy is case study (Yin 2003a) that means I have chosen a case that is deemed valuable both theoretically and empirically to be analysed. Moreover, while the case study can be used for different

purposes such as exploration, description, explanation, testing hypotheses and so on (Yin 1981), the prime aim of this research is explanation.

In case studies, theories play multiple roles in case studies "in the following areas:

a. Selecting the cases to be studied, whether following a single-case or multiple-case design…
b. Specifying what is being explored when you are doing explanatory case studies
c. Defining a complete and appropriate description when you are doing descriptive case studies
d. Stipulating rival theories when you are doing explanatory case studies…
e. Generalizing the results to other cases. " (Yin 2003b p. 5)

As this research is an explanatory study, the literature is being used to 1) identify a proper case with some interesting characteristics, 2) specify what is being explored, 3) stipulate the relevant theories for explaining the case, and 4) help to generalise the results to some degree after concluding the data analysis.

4.4. Theoretical Concerns of the Framework

In the last chapter, I formulated the theoretical research question, which is mainly concerned with the notions of frames and framing assumptions in analysing either the roots of policy controversies or the changes to policy outputs. In my efforts to find proper solutions for these theoretical questions, I need to use or develop a suitable theoretical framework as a set of tools to help and enable me to find the answers to those questions.

Therefore, in developing a useful theoretical framework, I focus on the concepts of the frame and framing assumptions as the main conceptual building blocks of the theoretical framework. This framework, in relation to the research questions, should help me in identifying the possible framing assumptions and their relations to the policy positions of the antagonists, which, I hypothesise, are in dispute with each other, and which have shaped the controversies within the system and between the DoE, MoS, MoA and MoH.

For this purpose, here I will discuss the application of the notions of frame and framing assumptions in the public policy analysis and risk and regulation literatures, as well as their possible contributions to developing such a framework. Before proceeding to this topic, first I will discuss the historical roots of this concept.

4.4.1. Frame: Origin and Development

Several scholars (Schon and Rein 1993, Van Zwanenberg and Millstone 2005, Jasanoff 2005) have claimed that the concept of 'frame' was originally introduced by Ervin Goffman (1974) in his sociological work about organising experience. However, reviewing the introductory chapter of Goffman's book reveals that he borrowed the term from Gregory Bateson's book, *A Theory of Play and Phantasy* (Bateson 1955).

According to Delanty and Strydom the seminal work of Goffman is part of an interpretative tradition "that developed in the wake of the earlier phenomenological and hermeneutic philosophies… advocated in different ways the need for social science to address common-sense forms of knowledge" (Delanty and Strydom 2003 p. 85). Hence, focusing on more subjective elements of knowledge renders an approach that "is interested in the cognitive processes and structures operative in every day life" (Ibid p. 87). Consequently, the meaning of a social fact should be viewed through the lens of the "cognitive processes, definitions, tacit forms of understanding, and practical reasoning that are constitutive of it" (ibid).

According to this view, Goffman opens his book by asking an old question, originally posed by William James: "*under what circumstances do we think things are real?*" (Goffman 1974 p. 2) He traces the arguments of James and their phenomenological roots and then the later developments in this respect, to ask a central question as the main concern of his work: how do people answer the question of 'what is it that's going on here?' in their everyday life when they face any current situation. By arguing that "definitions of a situation in the view of individuals are built up in accordance with principles of organization which govern events … and our subjective involvement in them", Goffman notes: "frame is the word I use to refer to such of these basic elements as I am able to identify." (Ibid p 10-11) In referring to "these basic elements", Goffman

means the basic elements of the subjective involvement of individuals in the situation, and 'frame' is a term he uses to refer to the integration of all these subjective elements in a coherent structure.

Although Goffman claims that his book is not about the organisation of society and the core matters of sociology, because they could be analysed without reference to frame at all, various fields currently use the idea of framing as one of their fundamental themes, such as media literature (Gamson and Modigliani 1989) or social movements (e.g. Benford and Snow 2000), and, as I pointed out in the previous chapter, some public policy analysis also uses this notion in controversy analysis (Schon and Rein 1994). This means that several scholars following Goffman adopted the concept of frame and used it for purposes other than his original intention.

In other words, Goffman uses the concept of frame to refer to the elements that he identifies in the mind-set of individuals when they become involved in a particular situation to understand how they organise their experiences, while some other scholars try to use the concept in analysing social events, like social movements, controversies and so on. Consequently, the notion of frame is not just being used as Goffman envisaged.

This differentiated use of the concept partly lies in the fact that some scholars have not based their work on the original contribution of Goffman, but instead have used the term with a different meaning for their study. For instance, Benford and Snow refer to Goffman by claiming that for Goffman, "frame denoted schemata of interpretation that enable individuals to locate, perceive, identify and label occurrences within their life space and the world at large." (Benford and Snow 2000 p. 614) This representation is different from that which I stated above and, by reference, to Goffman's book; we will find that the schemata of interpretation for Goffman was part of the definition of 'primary frameworks', which in turn is one element of the mind-set of individuals and an element of frame.

However, the concept of frame is applied by scholars in quite different ways, and I adopt a definition not strictly based on Goffman's own, but one that is useful for answering my research questions and that is mainly based on the literature reviewed in the previous

chapter. Therefore, in the next section I will discuss the development of the concept in the literature of public policy and subsequently in the literature of risk and regulation.

4.4.2. Frame and Policy Controversies

As I have discussed, the popularity of the notion of frame in policy analysis began with the work of Schon and Rein (1994). Before publishing a book in 1994, Schon and Rein wrote a chapter about reframing policy discourses (Schon and Rein 1993) in another book titled *Argumentative turn in policy analysis and planning*, edited by Fischer and Forester (1993). In that chapter, concentrating on stubborn policy controversies, Schon and Rein argue that those controversies cannot be understood in terms of separating facts from values, because participants hold the frames in which values, facts, theories and interests are integrated. They then pose a central question about resolving policy controversies: "what can possibly be the basis for resolving conflicts of frames when the frames themselves determine what counts as evidence and how evidence is interpreted?" (Schon and Rein 1993 p. 145) Schon and Rein stress that they "deal with policy controversies in the absence of an agreed-upon basis for resolving them." (Ibid) In other words, their main concern is finding a way to resolve controversies, considering that controversies normally arise from the conflict of frames.

Schon and Rein define framing "as a way of selecting, organizing, interpreting, and making sense of a complex reality to provide guideposts for knowing, analyzing, persuading, and acting", and thus "frame is a perspective from which an amorphous, ill-defined, problematic situation can be made sense of and acted on." (P. 146) On this basis, Schon and Rein define one aspect of critical policy analysis as an activity to identify the taken-for-granted assumptions that underlie people's understanding and actions, and the relationships between hidden premises and normative conclusions.

In 1994, Schon and Rein wrote a book about policy controversies, arguing that intractable policy controversies can be analysed in terms of frame conflicts, in which frames were understood as "underlying structures of belief, perception, and appreciation" that determine policy positions (Schon and Rein 1994 p 23). Moreover, they discuss the relationships between interests and frames by arguing that interests are shaped by frames

because the frames of "the actors determine what they see as *being* in their interests and, therefore, what interests they perceive as conflicting." (p. 29)

Frames can operate at different levels, which Schon and Rein (1994) classify into: 1) policy frames, 2) institutional frames, and 3) metacultural frames. A policy frame is one that underlies the definition of the policy problem in a specific policy situation. Institutional frames are those prevailing in particular institutions and which could affect the perception of individuals internal to that institution about the policy situation and the policy problem. Finally, there could be some cultural shared systems of belief in the form of metacultural frames, which are organised around generative metaphors like disease and cure, or nature and nurture.

In a paper published in 1996, Rein and Schon distinguished between four different meanings of a frame: 'scaffolding', 'boundary'[43], 'schemata of interpretation'[44] and 'generic diagnostic/prescriptive' stories. In adopting the fourth definition, which they referred to as 'metacultural frames' in their 1994 book, they emphasised the utility of metaphors to highlight the normative aspects of frames, especially when they suggest that such narratives not only explain what needs fixing, but also how it might be fixed, like the metaphor of a disease that needs a cure (Rein and Schon 1996).

In conclusion regarding the conceptualisation of Schon and Rein of the meaning of frame, it seems that their ideas have evolved through time to finally adopt the concept of a narrative as one to explain policy controversies. Nevertheless, even in their last contribution, they underlined the importance of a core element in all of the four definitions of frame: the existence of an assumptional basis (Ibid p. 88).

The concept of narrative has been substantially used and applied in different studies. For instance, Krogman (1996) analyses the Louisiana wetlands controversy by identifying three different groups according to their shared stories: 'regulators', 'regulated' and 'environmentalists'. The debates surrounding low-level radioactive waste in California has been analysed by Bedsworth et al (2004). They highlight three policy frames: the legal

[43] Intriguingly, Rein and Schon attribute this view to Goffman when he talked about selection of a stream of events. However, Goffman refers to this action as 'strips', not frames.
[44] Rein and Schon attribute this view to Snow et al (1986), while Snow himself borrowed the term from Goffman's concept of primary frameworks, and I referred to their 2000 paper in this respect above.

and scientific frame, the pragmatic frame that recognises the importance of down-to-earth matters, and the cautious and sceptical frame that reflects elements of environmentalism, justice and precaution. These narratives "lead to differences in policy actors' determinations of what are legitimate drivers for action, their bases for trusting claims, and their attitudes toward risk and uncertainty" (Bedsworth et al 2004 p. 408). The authors argue that these three contrary narratives imply different solutions and ramifications for solving the problem.

There are some variations to the concept of narrative as well. In the same book in which Schon and Rein (1993) discuss the importance of framing, i.e. the book edited by Fischer and Forester (1993), Martin Hajer provides an interesting analysis of the policy frames in the case of the British Acid Rain controversies by pointing to the fact that, although powerful vested interests played significant roles, the controversy itself signified a more fundamental conflict. He contends that "whether or not a situation is perceived as a political problem depends on the narrative in which it is discussed" (Hajer 1993 p. 44). In this sense, large groups of dead trees can be seen as the product of natural stress or as victims of pollution. The narrative of pollution in relation to the problem of environmental change might be linked to something bigger: the crisis of industrial society.

He extends the analysis further in a book published in 1995, and applies many elements of Schon and Rein's view: the policy problem, the policy situation and the narratives underlying different understandings of them (Hajer 1995). In this sense, Hajer tends to define narratives as general discourses representing broader perspectives that relate people from different backgrounds to each other without necessarily understanding each other (e.g. Keynesianism discourse). A discourse "orders the way in which policy actors perceive reality, define problems, and choose to pursue solutions in particular direction." (Hajer and Laws 2006 p. 261) However, as the case in Iran was limited to a few Ministries and a main Governmental organisation (i.e. the DoE), applying the concept of discourse as a very broad notion connecting several people might not be helpful. Nonetheless, I shall use the general characterisation of discourse by Hajer and Laws (2006) in my framework.

In short, while Schon and Rein were initially concerned about policy frames in policy controversies, they later tended to emphasise the importance of policy narratives as a means not only to define policy problems, but also to suggest how they might be resolved. However, this general definition does not imply a specific framework for study and it is up to the researcher trying to work with Schon and Rein's approach to review different documents and other sources deeply to extract the possible generic narratives, more on a trial and error basis.

This is the point that Schon and Rein stressed themselves, saying that "the difficulties in frame analysis lie in their fuzzy nature … the same course of action may be consistent with different types of policy frames and the same frame may lead to different courses of action; we have to deal with hybrid families of frames even within the same organisation; and sometimes it may be difficult to distinguish between conflicts within the same frame or cutting across different frames, or between real versus potential frame shifts." (Schon and Rein 1994 p 34-35)

Last but not least, there is yet another little considered point in the literature stream, which is the assumptional basis of different definitions of frames, either as narratives, as schemata of interpretation or as boundaries and scaffolding.

4.4.3. Framing Assumptions and Risk and Regulation

As I mentioned in the previous chapter, Wynne analyses controversies by applying a concept of 'cosmologies' as "a comprehensive system of thought which is rooted in social practice and experience." (Wynne 1982 p. 12) This concept is very close to the initial ideas of Schon and Rein (1993) in defining frames.

However, when Wynne applies these ideas in the context of scientific risk assessments, he finds the concept of framing assumptions a more useful analytical tool for that context. By pointing to the social aspects of risk and the experiences of risk assessments, Wynne (1992) makes a distinction between two components of framing: firstly, assumptions about relevant social behaviour, which is the source of differences in scientific reports –

such as presuming the same qualities for social organisations at times in the future – and secondly, framing of what is to count as risk for the purposes of social decision making.

These ideas, and the emphasis on the social factors that frame risk are echoed by Jasanoff (1993) in her editorial paper in the second issue of the journal *Risk Analysis* about the necessity of considering qualitative approaches along with the quantitative methods of risk assessment. She discusses different practical examples of the circumstances in which risk assessors make simplifying assumptions about the context within which the risk arises. The main argument of her article is that "what we claim to know about risk, how we acquire more information, and how we interpret facts in our possession are all contingent on contextual factors, ranging from individual or organizational experiences to national political culture." (Jasanoff 1993 p. 127) Hence, the concept of framing assumptions was first introduced in the beginning of the 1990s as the assumptions the risk assessors make in their quantitative, and presumed scientific assessments.

In their study to highlight framing issues in the context of risk assessment, particularly in the case of Herbicide-Tolerant Crops, Levidow et al (1997) borrow the idea of framing assumptions from Wynne (1992) and Jasanoff (1993), assuming that "technical evidence is inseparable from assumptions about nature and society" (Levidow et al 1997 p. 474), to discuss four disputed boundaries defining the role and limits of regulatory science in the context of European biosafety regulation. The four disputed boundaries discussed by Levidow et al (1997) are:

a. *Bounds of administrative responsibility:* this refers to identifying institutional responsibilities, while risk lies across (and not within) specialised current institutional responsibilities. In this sense, the EU bounds of responsibilities for GM HT crops remained unclear and disputed.
b. *Bounds of causality:* the scope of the risk and the risk-generating system is another contested boundary, as it was unclear which potential forms of harm to include and which to exclude from the calculations and decision making.
c. *Bounds of acceptable effects and control:* this mainly deals with the criteria of accepting effects and controlling measures to identify the boundaries within which the

effects are considered harmless, and the control measures provided for preventing harmful effects.

d. *Bounds of expertise and evidence:* this refers to identifying the relevant scientific disciplines to be included and responsible for risk assessment and those to be excluded, which in turn would affect the types and adequacy of evidence needed for safety judgments.

In comparison to Wynne (1992) and Jasanoff (1993), who emphasise the framing assumptions lying at the heart of risk assessment activities, or the social factors that affect scientific activities, Levidow et al (1997) extend the debate to argue that the four boundary issues are the matters that regulatory bodies should and do deal with, if only implicitly, and make decisions about. In this sense, although Levidow et al do not directly identify specific framing assumptions, they point to the boundary issues that should be considered by regulators. They further suggest that within each boundary, there might be several possibly conflicting framing assumptions.

This idea of looking at the disputed boundary issues that might reveal framing assumptions is interesting, and I will apply it as a part of my methodology. However, Levidow et al (1997) do not suggest a clear framework for identifying framing assumptions, and in analysing each case, the researcher should first identify the boundary conflicts and then try to find their underlying framing assumptions. In addition, another problem with this framework is its emphasis on the contested boundaries, while overlooking other disputed issues.

Some potentially useful literature about framing has been developed by Millstone and his colleagues in their attempt to reveal the sources of disagreements in trade disputes between the US and the EU *vis-à-vis* different products, among them GM crops (Millstone et al 2004). They conceptualise the framing assumptions as a part of the co-evolutionary[45] model, concluding that some sorts of framing assumptions, or what Millstone et al, following the Codex Alimentarius Commission, call Risk Assessment Policies (RAP), might account for the differences between scientific appraisals of risks

[45] Which I discussed in the previous chapter

across those jurisdictions. In this sense, they extend the initial ideas of Wynne (1992) and Jasanoff (1993) about framing assumptions in risk assessment experiments. Millstone endorses the suggestion of the Codex that those upstream framing assumptions (or Risk Assessment Policies) should be clarified and decided by regulators after consultations with risk assessors and other interested parties in advance of risk assessments. The result of Millstone et al's empirical studies (Millstone et al 2004, 2008) in terms of classifying framing assumptions are summarised (Millstone 2009) as:

1. "**Substantive** RAPs [which] are concerned with delineating which potential changes and effects are to be included within the scope of risk assessments and which are outside their scope, and which kinds of evidence are admissible and which are not…
2. **Procedural** RAPs [which] are concerned with the processes by which risk assessments are conducted and reported…
3. **Interpretative** RAPs [which] are concerned with the ways in which data are interpreted. Data and documents do not interpret themselves; interpretation often involves judgements and assumptions." (Millstone 2009 p. 631)

Some ideas behind this classification by Millstone are very close to the studies of Levidow et al (1997), as both scholars are concerned with framing issues in the context of biotechnology regulation and the importance of regulatory bodies in taking part in issues over framing. However, contrary to Levidow et al, who identify four disputed boundaries that might point to different sets of framing assumptions, Millstone tries to identify and classify the different types of framing assumptions in the experience of risk assessment, based on the experiences of countries within and beyond the European Union. I will use the results of these findings on different framing assumptions in my theoretical framework, though their classification of the types of framing assumptions might not be directly appropriate for the case of Iran, as the case of Iran was not a contention over particular risk assessments but over biosafety regulation on a more general level.

The work of Jasanoff (1995) on the three cultures of regulation in the USA, the UK and Germany underlies her later book, *Designs on Nature,* on the relationships between

politics and science in the case of agricultural and medical biotechnology (Jasanoff 2005). She adopts a narrative approach to framing biotechnology regulation, arguing that in policy making experience, particularly in science and technology regulation, story-telling produces some cognitive frames which "impose discipline on unruly events by creating understandable causal relationships, identifying agents of harmful behaviour, and finding solutions that convey a sense of security and moral order." (Jasanoff 2005 p. 24)

On this basis, Jasanoff defines three different cultures in the UK, the USA and Germany as "three controlling narratives that framed the course of policy development on genetic engineering". Respectively for these three countries, "(1) a novel *process* for intervening in nature, (2) a source of new *products* for the benefit of humans and the environment, and (3) a state-sponsored *program* of standardization and control carrying profound implications for human dignity and freedom, and raising questions of constitutional significance." (Jasanoff 2005 p. 39) [italics in original] In this sense, as Jasanoff is keen to discuss the effects of broad national culture on policy and science, her ideas are close to the notion of narratives adopted by Schon and Rein (1996) as the generic factors underlying the perspectives of those three advanced countries regarding biotechnology regulation. In this sense, Jasanoff extends the analysis to discuss the framing of regulation, though by applying the notion of narratives rather than that of framing assumptions. Nevertheless, a problem in this study is that it seeks to explicate the differences between the three countries and their ways of framing biotechnology by a single factor, i.e. their narrative about biotechnology, which might not provide a satisfactory framework for the purposes of my analysis.

Murphy and Levidow (2006), in their analysis of the transatlantic conflicts over agricultural biotechnology, apply the concept of framing to the policy discourses that shaped three different policy dialogues across the Atlantic. (As I discussed earlier, discourse is a type of very broad narrative, developed by Hajer 1995.) They identify three groups linked together based on their beliefs and policy discourses, while the dialogues between those discourses, according to Murphy and Levidow, shape the conflicts between and within both the USA and the EU.

The three dialogues are: 1) Transatlantic Business Dialogue, promoting trade harmonisation, 2) Transatlantic Consumer Dialogue, promoting the right of knowing and choosing for consumers, and 3) Transatlantic Environmental Dialogue, seeking proof of safety of agro-biotech products. Murphy and Levidow also analyse the dynamics of evolution in the interaction between those three discourses. In this way, they suggest an approach for not only analysing the transatlantic conflicts, but disputes within territories. However, there were not such policy discourses and dialogues in the case of Iran, as most of the controversies took place between governmental departments and behind closed doors, which in turn undermines the usefulness of the discourse approach for the case of Iran.

Levidow and Carr (2009) build on the previous analysis of Murphy and Levidow (2006) analysing the GM food trial policy in the context of the EU to cast more light on what they call the democratic deficit in the EU experience. They use the concept of framing based on Rein and Schon's definition as a "way of selecting, organizing, interpreting, and making sense of a complex reality." (Rein and Schon 1991 p. 263 cited in Levidow and Carr 2009, p. 38)[46] Accordingly, they make a distinction between three discursive frames across the agro-biotechnology policy arena: agro-biotech promoters, state bodies, and agro-biotech opponents, each holding different views over issues of policy making such as innovation and regulation, risk and sustainable agriculture, GM labelling and agricultural futures.

Although this framework has proven to be useful for analysing the experience of European agro-biotech regulation by distinguishing between the frames of the involved actors, it might not be useful for developing a framework for the case of Iran, as in Iran the controversies were between governmental agencies without participation of other types of actors.

In short, the Sociology of Scientific Knowledge (SSK) literature on biotechnology and risk regulation started from the analysis of Wynne (1982) about the Windscale nuclear

[46] Although they refer to Rein and Schon 1991, it seems that there was a typographical error in the book because there is no such publication in 1991 by Rein and Schon; presumably the 1993 publication was intended

controversies, then shifted to applying the concept of framing assumptions to risk assessment experiences (Wynne 1992, Jasanoff 1993, Stirling 2008) and consequently to applying the concept of framing assumptions in explicating the differences between the outputs of risk assessments in jurisdictions, and the role of regulators in identifying or making explicit risk assessment policies (Millstone et al 2004, 2008). Other applications of the concept include: framing with regard to the contested boundaries in biotechnology risk assessments in the context of the EU (Levidow et al 1997), policy discourses and dialogues as a major source of emerging transatlantic conflicts (Murphy and Levidow 2006), three different policy frames shaping the EU GM food trial conflicts (Levidow and Carr 2009), and delineating the differences between the UK, the US and Germany over biotechnology regulation by applying the concept of narratives (Jasanoff 2005).

This evolution shows that the concept of framing in the literature of risk and regulation can also be used for a variety purposes as there is considerable flexibility in the concept of framing and framing assumptions. As tracing the trends of intellectual evolution shows, other literature strands have started to borrow the notions of frames, narratives and discourses from the literature of public policy to develop useful frameworks for their studies (such as Jasanoff 2005, Murphy and Levidow 2006 and Levidow and Carr 2009). However, as I argued above, these literatures cannot propose a framework suitable for analysing the controversies and changes in the case of biosafety regulation in Iran. Moreever, these studies have been mainly based on national cases and differences and disputes between countries, without paying considerable attention to possible internal conflicts within countries.

Hence, in the next section I will try to develop a framework for this study by deploying the insights from the literature of both public policy analysis and risk regulation as a way to develop a novel perspective and perhaps one that is more generalisable in comparison to previous work.

4.5. Developing a Framework

In developing the framework, first of all I will clarify the unit of analysis with respect to the meaning of frame that I intend to apply, and then I will discuss the other elements of the framework of this study.

4.5.1. Units of Analysis

For the purpose of developing a useful framework focusing on the notions of frames and framing assumption, it is worth recapping the two broad meanings of the concept in the reviewed literature:

a. Frame as a generic narrative, or a type of discourse that frames the views of protagonists, and which is mostly used in studies on public controversies, mainly following the contributions of Schon and Rein (1993, 1994, 1996) and Hajer (1993, 1995). These notions have also been applied by scholars in the field of risk regulation like narratives used by Jasanoff (2005), discourses applied by Murphy and Levidow (2006) and frames used by Levidow and Carr (2009) to explain differences and conflicts over biotechnology policy and regulation.
b. Frames as framing assumptions, broadly discussed in studies about the experience of risk assessments and used to explicate how these assumptions might frame the results of risk assessments (Wynne 1992 and Jasanoff 1993) and eventually lead to different regulations between countries (Millstone et al 2004, 2008).

For the purpose of the current research, I will use the concept of a 'framing assumption' as a basic unit of analysis for several reasons that in turn might offer a novel aspect to the framework, as framing assumptions have not been considered as a basic concept for analysing regulation, but instead have mainly been used for analysing risk assessment experiences.

The first reason for this lies in the difficulty of applying the concept of narratives, as the literature does not suggest a theoretical framework for how to use this concept for the purposes of analysis that render a type of exploratory research subject to interpretation.

As a motivation for developing a more general framework for analysing policy controversies, and possibly policy changes, it seems that by applying the notion of framing assumption and coupling it with some insights from the literature on public policy analysis, this objective might be realised.

Secondly, although the concept of narratives has been applied to both the contexts of intra- and inter-governmental disputes, studies on biotechnology risk regulation have highlighted several particular framing assumptions that might also be important in the case of Iran, as it was a case of biotechnology and risk regulation, which might otherwise be overlooked.

Thirdly, and linked to the second reason, as Schon and Rein (1996) suggest, narratives have a strong assumptional basis that means even when using the concept of narratives as the basic unit of analysis, there might be some unexplored assumptions that in turn might jeopardise or limit the explanatory power of the research. However, focusing on the framing assumptions may provide a better explanation of controversies and policy outcomes and probably a better understanding of the assumptional foundations of narratives. In addition, framing assumptions might be more easily linked and matched to the theories of idea-based policy analysis.

As assumptions might be defined at several levels, i.e. individuals, groups, organisations or countries (Schon and Rein 1994), I will consider the assumptions of the organisations involved in the process of negotiation for drafting the biosafety law as the contentions were originally between the Ministries and organisations over the three phases of negotiations and behind closed doors. In this sense, I will not adopt the idea of considering coalitions of groups as a basic unit of analysis (e.g. Sabatier and Jenkins-Smith 1993 or Hajer 1993, 1995) because of the special structure of that policy process in Iran.[47]

[47] For instance, the case of conflicts in China about GM cotton and GM rice has been analysed by Keeley (2006). According to his analysis, there are many similarities between the structure of biotechnology in China and Iran in a way that government plays a very important role in biotechnology development in China and negotiations were held behind the closed doors. However, Keeley (2006) applied the concept of discourse coalitions to identify the groups which were joined together because of the similarity of their ideas. However, as I mentioned before, the case of Iran is different as it was a contention between organizations and ministries about the biosafety law throughout the time.

4.5.2. The Suggested Framework

I have constructed a framework by borrowing from both streams of literature that in turn also inform my methodology. The intricacy of this work is in linking two broad sets of literature, each of which with its specific concerns and developed in different contexts. I have tried to suggest a framework that will integrate the insights of those two streams of literature for the purposes of identifying framing assumptions in the context of Iran.

On one hand, I use the literature on public policy analysis to suggest a general framework for identifying the different aspects of the policy the definitions of which might be constructed based on different framing assumptions. This framework might also provide (partial) theoretical confidence that several relevant aspects of the policy making experience are considered. On the other hand, the empirical studies on risk assessment framing assumptions have already identified several framing assumptions in other countries, which could be located in the general framework resulting from public policy analysis literature, which in turn could provide the substance of that framework.

For instance, in the literature on public policy analysis, Schon and Rein (1994) talk about differences in understandings about policy problems due to different framing assumptions. They also point to different understandings from problematic policy situations that might lead to different formulations of policy problems. This classification means that a researcher could search for definitions of those two elements, as a type of framework, to search for their underlying framing assumptions.

This framework could be completed by locating the framing assumptions identified in the studies on risk assessment framing assumptions. For instance, Millstone et al (2004) count different assumptions about the scope of the risk as whether it is short term or long term, considering direct or indirect effects, and covering only target or also non-target organisms. These sorts of assumptions might also be present in the case of Iran, and the research could search for signs of similar assumptions in that context. In addition, I will consider a variety of possible types of assumptions in my framework.

In other words, my theoretical framework has two dimensions. I will use the literature on public policy analysis to classify the diverse aspects of policy making on which their definitions might be constructed based on various framing assumptions, such as what counts as a policy problem, and by scrutinising the definitions of those aspects, I will try to identify different framing assumptions. The literature on regulating biotechnology and risk, in complement, could help in pointing to possible framing assumptions that might be present in the case of Iran and therefore might lead to different definitions of the identified aspects of policy making.

On this basis I suggest the following framework for characterising the policy aspects that might be differently understood based on different framing assumptions. I will later complement this framework by particular framing assumptions:

a. *The identification and characterisation of the 'policy problem' that needs to be resolved*
b. *The 'risk system', including the risk-generating system that was accounted as the source of risks as well as the scope of risks that signify the border of causalities within that system*
c. *The 'policy prescriptions', or the ways of addressing the problem and the problematic situation.*

This framework borrows from the suggestion of Hajer and Laws (2006) that a policy discourse constitutes three elements, reality, problems and solutions, which in turn cover the previous characterisations of Hajer (1993), Schon and Rein (1994) and Rein and Schon (1996) in which the former two point to the policy problem and policy situation, and the latter refers to the problem and the ways of addressing it. However, the risk system is similar to what Levidow et al (1997) have discussed as boundaries of causalities, including the scope of the risks and the risk-generating system.

These three dimensions of policy making might be understood differently based on different assumptions of the contending protagonists, which in turn might affect their overall approach about biosafety regulation. For instance, what are the problems? What are the elements of the system that lead to the problems, and how are causalities defined

in this system? And what policy suggestions could lead to resolving the problems? All might be understood differently based on the different framing assumptions of the protagonists.

Hence, instead of integrating them under an umbrella to call them a single policy discourse or narrative, I will seek to explore the various assumptions involved in defining each of the above policy aspects (a-c) by applying the insights of studies in the literature of risk regulation. For this purpose, I will try to locate the variety of framing assumptions identified by that literature relating to the above policy aspects (a-c), as those assumptions might also be present in the case of Iran. However, this does not mean that the framework is confined to those provisionally identified framing assumptions, but just that they represent some possible framing assumptions.

1- Framing assumptions affecting definitions of policy problems:

As a possible point of disparity, protagonists might adopt different definitions about the policy problems that need to be considered and addressed, due to prior framing assumptions. As for the case of biosafety regulation in Iran, this means that although different organisations negotiated over the proper biosafety law for the country, it is possible that they adopted different definitions of the policy problems that should be resolved through enacting a biosafety law. For instance, the problem might be seen by one Ministry as finalising a law, while for another it might be minimising the risks of biotechnology, or exploiting the benefits of this technology. In defining such problems, protagonists might have several framing assumptions that affect their formulation of the problem at hand. The following assumptions might be present in the case of Iran:

a. Different assumptions about biotechnology might lead to different formulations of the policy problem. For instance, Jasanoff's (2005) account of biotechnology as a novel product, a process or as a programme is one possibility.
b. Even when rejecting or undermining the risks of biotechnology as a central assumption, some protagonists might have different assumptions that in turn affect their understanding of policy problems.

2- Framing assumptions affecting definitions of the risk system:

A risk system is a system composed of risk-generating system as well as the scope of those perceived risks. This system might be understood differently by protagonists and for each Ministry or organisation, some elements might be perceived as more important than others, and the roles of those elements might also be envisaged differently. Two parts of this risk system are particularly important, the sub-system that is believed to contribute to generating risks, and the sub-system that is impinged by the impacts of those perceived risks and the causalities that define the border of impacts (i.e. scope of risks). Therefore, this system covers several socio-technical and ecological elements, and could be understood differently because of the adoption of different framing assumptions by protagonists, such as:

a. Assumptions that organisations adopt about each other (e.g. Wynne 1982)
b. Ideas about future uses of products in the system: for export or for domestic use
c. Assumptions about the causalities within the system, as referred to by Levidow et al (1997), or what Millstone et al (2004) count as the scope of the physical risks including risks to the human health as well as environment
d. Another scope of risks could be political, social or cultural risks, in addition to the physical risks, which are discussed by Jasanoff (1995)
e. Assumptions about external contexts such as understanding of other countries' approaches, the role and interpretation of CPB and so on
f. Other possible assumptions in envisaging the socio-technical system and its borders that I will try to identify, such as the importance of considering Iran as a developing country and its different possible interpretations.

3- Framing assumptions affecting definitions of policy prescriptions:

Even if the antagonists have similar ideas about the risk system and policy problems, there might still be differences in their views on how to address policy problems in that particular situation because of the adoption of different framing assumptions. These assumptions could be:

a. Which structural mechanism should be applied for managing and administrating biosafety in order to confront the problem. Figure 3-6 in the previous chapter provides an account of the assumptions behind those models in terms of the assumptions about:
    i. Whether or not science and scientific judgments are neutral
    ii. Whether or not science can provide sufficient answers to policy problems
b. Assumptions about the benchmark of decision making (for instance whether to trade off risks and benefits, or how to do that in terms of distributional comparisons, minimising risk, or maximising benefits), which in turn suggest how to confront the problem.

4- Other assumptions:

Although I have tried to construct a framework including most of the relevant literature, there might be other assumptions that cannot be captured by those categories. Therefore, the data analysis will remain open-ended.

4.6. Research Methodology

The methodology applied to the current research is largely determined by my theoretical framework, along with the empirical topic as well as the selected context. After explaining the scope of the research including the actors to be considered and the time span of the study, I will discuss the data requirements, data collection and data analysis accordingly in this section.

4.6.1. Actors

The four most prominent Governmental organisations in the Iranian regulatory system *vis-à-vis* biosafety are: the Department of Environment (DoE), the Ministry of Health (MoH), the Ministry of Agriculture (MoA), and the Ministry of Science (MoS). The DoE has been involved in the issue since Iran's ratification of the Biodiversity Convention in 1996. In January 2006, this department was selected as the office of the secretariat for

the National Biosafety Committee (NBC) by the Cabinet, and the head of that office was also the senior representative of the DoE to the Coordinating Committee (CC) sessions.

The MoS has a large institute of genetic engineering and biotechnology named the National Institute of Genetic Engineering and Biotechnology (NIGEB), which works on the development of biotechnology fields including medical biotechnology, plant biotechnology, animal and marine biotechnology, industrial and environmental biotechnology and basic sciences. This institute was established in 1989 to work on both medical and agricultural biotechnology and the senior representative of this Ministry to the CC sessions was a chief scientist from that institute who was also the chair of an biosafety committee within NIGEB.

The MoA is the main body responsible for providing agricultural goods and helping Iranian farmers, who mainly work on their own farms. The Agricultural Biotechnology Research Institute of Iran (ABRII) of this Ministry, which was established in 1983, was the place in which the Iranian GM rice was first developed in 2004. ABRII is the relevant institution in the MoA that has been involved in drafting the biosafety law in Iran, and the senior representatives of the MoA on the CC was the head of this institute, receiving advice from its many other biotechnological experts.

The MoH conducts substantial research activities in medical biotechnology. The Pasteur Institute is the leading organisation in developing biotechnological medicines in Iran. This Ministry was also involved in the biosafety law drafting process from the outset. The Pasteur Institute of Iran mainly handles the biosafety issues in this Ministry, and the senior representative of this Ministry to the sessions of the CC was a chief biotechnology scientist from this institute.

4.6.2. Time Span

Although the CPB was ratified by the Iranian Parliament in August 2003, the controversies about biosafety regulation did not officially emerge until 2006, when the DoE invited other organisations to present their views in the negotiating sessions over a draft biosafety law. Thereafter, different organisations put forward their opinions about

biosafety and the necessary legislation, which in turn generated increasing controversy about the content of the biosafety law. In Chapter 2, when describing the context, I elaborated on the two periods of historical debate over biosafety, before and after 2006, and this research will focus on the second period, from April 2006 until the passing of the law by the Parliament in May 2009. This period is itself composed of three stages of negotiations, namely the CC sessions, the Reviewing Committee (RC) sessions and the Parliamentary sessions. The empirical chapters will therefore be organised to cover those periods in chronological order.

4.6.3. Data Sources

Patton (2002) counts three different sources of qualitative data, which are: 1) interviews, 2) documents, and 3) observations. I shall use all three types of sources for the purpose of the current research.

Documents include inter- and intra-departmental letters, the formally presented opinions of the relevant organisations that mainly came out after a two-day gathering about the biosafety law (which was held just after the end of the CC sessions to finalise the draft law), internal reports, and other formal and informal hand-written and typed papers, along with public and media interviews by institutional actors.

I also conducted several interviews over two periods. The first round of interviews was conducted in summer 2008 when the draft law was sent to Parliament, and the second round in summer 2009 when the law was passed by Parliament. In each period, I interviewed senior representatives of each of the four organisations.

Although I observed the behaviour of the organisations during the period of research to some extent, my main source of observation was the official voice recordings of the negotiating sessions, including the tapes of the CC sessions, the tapes of the two-day gathering, the tape of the National Biosafety Committee (NBC) session and the tapes of the RC sessions. Listening to the opinions and arguments of the organisations over nearly 30 sessions provided a rich source of data to identify and analyse the framing assumptions.

4.6.4. Process of Data Collection

I conducted the first round of interviews and data gathering in summer 2008. During that period, I contacted senior representatives of the four organisations and obtained some initial documents, as well as conducting interviews with them. However, the main task of data collection was carried out in summer 2009 when I went to Iran to complete gathering the required data.

In this second period, I was looking for more data about the perspectives of the protagonists on the biosafety law, especially their opinions as presented in the different sessions over the legislation of biosafety. I asked the protagonists to allow me access to the records of the negotiating sessions. In addition to these efforts, I also tried to develop closer connections to the protagonists to establish a form of participant observation looking at their general approaches and asking some questions about the biosafety law at different opportunities.

As a result of interactions with the MoH, I established a very close connection with the main contact in this Ministry who had been involved in the biosafety legislation process. I met him frequently in that period, each time asking for more information relevant to my project, or my dissertation. He helped considerably in accessing the letters and documents of this Ministry.

During this time, Agricultural Biotechnology Research Institute of Iran (ABRII), the biotechnological research centre of MoA, held a course on risk assessment and its rules and guidelines. Registering for this three-day programme, I visited ABRII and asked new questions of the head of this department as the main person involved in the process of legislation. Moreover, I was then able to access more documents, especially the Ministry's reports concerning different versions of the draft biosafety law. Last but not least, the institute presented their opinions on risk assessment and risk management in the course sessions, especially on the first day, which provided substantial information on how they see and analyse biosafety.

Another opportunity was provided by the representative of the MoH; I was invited by a chief biotechnological expert in the MoS, who represented the views of this Ministry in the legislative process, to present my initial findings as a keynote paper in the Sixth National Congress on Biotechnology in Iran, the most important scientific event in this field, held every two years. This event gave me the opportunity to participate in a three-day programme, talking with different biotechnological experts. Intriguingly, I found many experts working in universities to be agnostic about the process of biosafety legislation in the country, while at the same time I was able to ask more questions of representatives of the involved Ministries with respect to my work. Consequently I was able to go to an office in the MoS which held several important documents of which I was able to obtain copies.

In parallel, I tried to convince the DoE, as the office of the secretariat of the NBC, to allow me access to the voice recordings of the negotiation sessions. After two months of negotiating with DoE, alongside testing other informal linkages, the head of the office finally allowed me to go to DoE and listen to the cassette recordings, without permission to take them away or copy them. As a result, I spent around three weeks going to the office of the secretariat to listen to and make notes about the sessions. Incidentally, during these three weeks I became familiar with the DoE's everyday work. Eventually, and possibly because of a change of the head of the DoE, the head of the office let me copy the voice recordings as an original source of data, covering almost all the negotiation sessions.

4.6.5. Data Analysis

In applying my theoretical framework, I will look for definitions of policy problems and definitions of the risk system as well as policy prescriptions to identify the possible framing assumptions. In this way, the suggested theoretical framework should be helpful in analysing data. It points to the dimensions of the policy that might indicate or reveal different framing assumptions. Therefore, I will look for indications of assumptions defining the risk system, policy problems or the prescriptions for resolving problems. Searching for definitions of those three elements could be seen as a search at the general

level in comparison to the parallel search, in which I will search for any sense of the identified framing assumptions in the literature of biotechnology risk regulation to find out whether or not they, or similar notions, were present in the case of Iran. This could be seen as a search at particular levels. Thus, the movement from general definitions to particular assumptions can be complemented by the parallel movement from particular assumptions to general definitions, which together might yield a convergent analysis or facilitate triangulation.

Further, I shall consider the approach of Levidow et al (1997) indicating that the framing assumptions might be found in the highly contested boundary issues, and will consider the controversies that erupted (not just related to boundary issues) during the sessions as a main place that might reveal further framing assumptions. However, this does not undermine the importance of considering all the debates and discussions throughout the sessions, rather than just focusing on the disputes that erupted.

I will conduct this analysis at three different stages of the negotiations. I will first analyse the first round of negotiations, including the CC sessions and the subsequent two-day gathering that ended without any clear result. I will similarly analyse the NBC sessions as well as the RC sessions as the second stage of negotiations, and then I will similarly analyse the available data for the third stage of Parliamentary discussions.

Thus, for each stage I will have a table, similar to Table 4-1, which is the simplified diagrammatic representation of key elements of my framework, including the framing assumptions of the organisations with regard to policy problems, the risk system, and the prescriptions for resolving problems. Populating the empty cells of the table will provide a set of resources concerning to what extent these organisations hold different framing assumptions that in turn may provide an explanation of the controversies.

The differences between the framing assumptions should suggest the degree to which framing assumptions might have underlain the controversies. The results of the analysis will show the extent and degree of differences and will highlight the points where the contrasts are sharper. In connection to the background picture represented in Chapter 2

about the context of other countries, similarities to and differences from the debates of those countries may also emerge at the end.

Table 4- 1A sample of data analysis table

	MoH	MoS	MoA	DoE
Assumptions affecting understandings of the nature of policy problems				
Assumptions affecting defining the risk system				
Assumptions influencing the policy prescriptions				
Other				

Finally, a comparison of evolving versions of the table as a result of analysing three rounds of negotiations will be used for analysing the dynamics of the process. I will compare the versions of the table to find possible changes in framing assumptions and their possible connections to changes in the policy outputs. If I find a considerable change in the framing assumptions that could help to explain changes in the policy outputs, the question will then be why and how those framing assumptions have changed, and also why the controversies were not resolved if the framing assumptions changed. If I find that the framing assumptions remained unchanged, then the question would be why policy outputs changed while framing assumptions remained unchanged.

In the next three empirical chapters, I will discuss the three stages of negotiations respectively, trying to identify the diversity of the protagonists' framing assumptions in order to populate the analytical table and characterise its cells, which in turn might help find the answers to the research questions and the factors underlying policy controversies and policy changes in the context of biosafety policy making in Iran.

Chapter 5. The first phase of negotiations: Coordination Committee and Two-Day gathering, May-December 2006

5.1. Introduction

As stated in the final part of the previous chapter, the aim of the remaining empirical inquiries is twofold: to explain the controversies as well as the policy outputs through eliciting the framing assumptions of the four major organisations involved in the process, i.e. MoA, MoS, MoH and DoE.

The current chapter examines the first stage of the negotiations towards the biosafety legislation, which lasted nearly eight months from May to December 2006, chaired by the head of the office of the secretariat of the NBC located in the DoE, who at the same time was representing the views of the DoE. Therefore, I shall refer to the chair of the sessions and the head of the office interchangeably.

In this phase, representatives of the organisations participated in the negotiations, called the Coordination Committee (CC) sessions. The invited organisations at the beginning were: the Ministry of Trade (MoT), the Ministry of Industry (MoI) and the Ministry of Foreign Affairs (MoFA) as well as the four major organisations mentioned above. The MoT and the MoI were only participating in the sessions to be informed about the content of the future law;[48] and the MoFA was mainly concerned with the international aspects of biosafety regulation with respect to Iran's commitments to the CPB. However, the representative of the MoFA was nonetheless involved in the more sophisticated levels of discussion mainly because of his personal interests.[49] The MoA, MoH and MoS sent biotechnology experts from their biotech research centres as their senior representatives.

Therefore, concentrating on the main four organisations of the study, in this chapter I am going to discuss the relationships between framing assumptions and the controversies as well as the policy output of this stage. For this purpose, I will first elaborate the administrative and procedural features of the negotiations that were mainly articulated in

[48] This is what their representatives indicated in interviews. The voice recordings of the sessions also confirm that they had not been involved in the topics.
[49] However, the MoFA did not participate in the later stages of negotiations (i.e. Reviewing Committee).

the first session of the CC. In the light of this characterisation, I will show how the main points of disagreement were postponed by the chair of the session to the two-day gathering, which was held after ten sessions of the CC.

I will then turn to the two-day gathering which was mainly aimed at finalising the draft law as the next step. This congregation ended with clashes between the members without any clear result. Elaborating the successive sessions of the two-day gathering, I will delineate the main points of conflict and show how the members could not proceed beyond Article 3 of the 20 articles of the draft law, at which point disputes erupted on the second day and continued up to the point when the members decided to leave the session.

I will concentrate on framing assumptions to show how some important and different framing assumptions underlay the disagreements between Ministries and departments. I will use a variety of relevant data sources, like documents and letters published before and after the two-day gathering, in addition to the voice recordings of the sessions. In some contexts, it has not been possible to identify the framing assumption of a certain organisation *vis-à-vis* a specific topic. This is partly because the representatives preferred to stay silent in certain debates, while the available documents up to that point also may not be adequate for extracting their framing assumptions on that particular topic. For instance, the MoA did not enter into the discussion over the opening clauses of the law, which in turn posed a difficulty in understanding its assumption about biotechnology.

Therefore, the partly-elaborated table at the end of this chapter remains incomplete. Its empty cells will be populated in subsequent chapters, some in the elaboration of the NBC committee and the Reviewing Committee (RC), and some through using the information that has come from interviews and documents. Finally, I will discuss the extent to which the framing assumptions can contribute to explaining the policy output of this stage.

5.2. Overall procedural and administrative features

The CC was an intermediate committee between the NBC and the Ministries and organisations before 2006. This committee was composed of representatives of the

Ministries and organisations and its purpose was to discuss various issues pertaining to biosafety. The new office of the secretariat in the DoE asked other Ministries to introduce their new senior representatives to the CC to work on drafting the law that incorporated their variety of perspectives.

After ten sessions to discuss the draft, the members came together in a two-day gathering to finalise it. However, that gathering ended with clashes between members without any clear result over the draft law. In the following parts of this chapter, I will highlight the procedural and administrative features of those sessions. Five characteristics of the sessions are imperative in gaining a better understanding of the procedural and administrative processes.

5.2.1. Discussing a preliminary draft as the memorandum of meetings

The first point refers to the memorandum of the sessions. In the first session, all Ministries endorsed the decision of the office to bring Ministries and the DoE together for the sake of incorporating different views of the biosafety law. Consequently, the members suggested not wasting time on the previous drafts prepared in the individual organisations. Instead, they asked four people – none of them formally representing a Ministry – to prepare a preliminary draft as the basis for discussions in the future sessions.

This team spent a great deal of time over a fortnight (between the first session, which was held on 24 May and the second one on 7 June 2006) to produce a new and preliminary draft as the basis of discussions in the future CC sessions. Consequently, this draft shaped the memorandum of the meetings (MOM), based on which the members took part in the sessions, read clause by clause, put forward their opinions and sometimes continued discussing over the challenging points.

5.2.2. Rush over finalising the draft by the chair of the sessions

The second point was the office of the secretariat's hurry to stop various discussions and finalise the draft as soon as possible. The urgency for finalising the draft was reflected in

the opening speech of the head of the office in the first session of the CC held on 24 May 2006. He argued that:

- The most important task was finalising the draft law as soon as possible.
- There seemed to be few previous draft versions, prepared by MoS and DoE.
- It was undesirable to start the work from beginning; instead, the current available drafts could form a starting point.
- It might therefore not be necessary to go through the details to finalise the draft.
- He hoped that after four sessions, not only a general agreement would have been reached, but also that considerable materials would have been prepared to be approved by the NBC.
- On that basis, he hoped to be able to hold the NBC session within two months.[50]

During later sessions, the head of the office continued to emphasise the necessity of finalising the draft as soon as possible. Further, whenever a serious or basic discussion arose, the head of the office tried to bring it to an end, sometimes by pointing to the sufficiency of the discussion, sometimes by claiming that there was no substantial difference between contested points, sometimes by postponing the issue, promising it could be discussed by more detail at the two-day gathering, and sometimes by pretending that the arguments were complementary to each other.

The sessions of the CC were replete with examples of interventions by the chair of the session mainly for the sake of ending debates. For instance, at the start of the second session, a member read the suggested text for the opening clauses of the draft as: "although modern biotechnology bears certain benefits for humans, we should not forget the possible hazards of this technology…"[51] A biotechnological scientist who was not a formal representative of an involved organisation, but an expert who had been invited to participate in the negotiations, stated that "this type of beginning might not be

[50] Official voice recordings of the first session of the CC held on 24 May 2006 (author's translation).
[51] The preliminary draft biosafety at the beginning of CC. I don't have a copy of this draft, but it was all read in the sessions and this statement was the beginning of the opening clauses which was read in the second session of the CC according to the voice recordings.

appropriate because it directly expresses concerns about biotechnology, while we know that biotechnology development is also among the goals of the country."[52]

The MoFA replied that this reflected a general principle of the CPB with respect to biotechnology, and the MoS suggested that it may be better to first list the benefits of biotechnology and then move onto safety concerns. Discussions continued over whether or not this would be a good opening statement, until the chair of the session interrupted them by saying: "although I know having deep discussions would be helpful, we should consider the time as well. We need to finalise the law as soon as possible. Having expressed these concerns, I would suggest the members of the team who prepared this preliminary draft to sit down and revise the opening clauses again. So let's move to the next part of the draft."[53] This type of intervention happened frequently.

5.2.3. No proper acknowledgement of controversies by the office

In relation to the previous point about the rush over finalising the law, the office of the secretariat located in the DoE to a large extent denied or perhaps did not recognise the existence of principle disagreements and the many diverse framing assumptions. I was able to access an interesting document prepared by the office that shows how the office articulated the different opinions of the organisations, but did not point to their framing assumptions, after the clashes of the two-day gathering.[54] This document tried to highlight the differences between organisations and is divided into several parts; the first section is titled "general principles". Other parts of this document listed the opinions of the Ministries as well as the DoE over provisions of the draft, such as the location of the office, the process of authorisation for releases, prosecutions and so on. In the first section about the general principles, the document merely stated:

"*MoA:*

1- *The law should cover and fill our current legal gaps*
2- *It should not contradict the current duties of organisations*

[52] Official voice recordings of the Second session of the CC committee held on 7 June 2006 (Author's Translation).
[53] Ibid
[54] I have a copy of this document from the office. Its title can be translated as: "Summarising the opinions after the gathering". Although it is undated, it was prepared after the two-day gathering.

3- *It must not create an overlap between responsibilities of organisations or shift the duties from one organisation to another*
4- *The law should not be reduced to operational rules*
5- *The duties suggested for organisations by the CPB need to be considered.*

MoH:

1- *The law should not become a barrier in the way of research*"[55].

However, the document provided no other information about, or characterisations of the approaches of those Ministries. This primarily shows that the office did not acknowledge the principal differences in perspective between the Ministries and the DoE, even after the big clash at the end of the two-day gathering.

5.2.4. Lack of sufficient discussion over the meaning of biosafety

Fourthly, the members did not use their time to discuss their understandings of biosafety. It is intriguing for me to see how they wasted a great deal of time in the sessions without discussing biosafety in any detail. The roots of this phenomenon can also be traced to the first session. After agreeing to discuss the preliminary draft to be developed by the independent team, the MoS suggested identifying the general principles (or what it called a framework) in the remaining time of the first session as an intellectual input for the independent team. For this Ministry, the ultimate requirement was having a clear understanding of the definition of biosafety in particular, as well other definitions required for developing the draft.

The MoS then went on to propose its own suggestion about the meaning of biosafety by defining which matters were to be included as biosafety. Meanwhile, the MoH changed the topic from defining biosafety to remarking on the differences between organisations, by pointing that the "definition of biosafety might be different in the Ministries and organisations involved. This fact calls for the necessity of holding a session within which every department present its own perspective on biosafety. A general agreement in that

[55] Ibid

session could lay the foundations for writing the draft."[56] This suggestion by the MoH was rejected by the other members, who mainly pointed out that this process would be time-consuming and might even lead to substantial disputes.

Members subsequently agreed to adopt the definitions of the CPB as the basic definitions of the preliminary draft. After this, there was little discussion over the definition of biosafety.

5.2.5. Consensus-based decision making

The last but not the least point is regarding the general presumption by all members that every decision should be based on a consensus. However, there was no clear mechanism for obtaining consensus; instead, consensus would be obtained if there was no clear opposition in the session.

Now I turn to the next section; for this purpose I will concentrate on the two-day gathering for two reasons. Firstly, many issues were postponed by the chair of the CC sessions who promised that they could be discussed in more detail at the two-day gathering. As a result, members generally ceased seriously pursuing the debates in the CC meetings. The second reason, which has to do more with the practicalities of writing a dissertation, lies in the fact that it would not be possible to present and elaborate all the data (ten sessions of the CC, each around two and a half hours, and eleven successive sessions of the two-day gathering, each close to two hours) in an empirical chapter.

5.3. Framing Assumptions

This section is organised in a way that first of all provides a general introduction to the two-day gathering, followed by highlighting three important framing assumptions which were reflected in three heated and unexpected disputes among the members.

The purpose of the two-day gathering was to finalise the draft to be passed to the Cabinet and finally to Parliament. The head of the DoE joined the beginning of the session and delivered a short speech to show her respect for what she called the "sincere efforts" of

[56] Official voice recordings of the first session of the CC on 24 May 2006 (author's translation).

the representatives of Ministries and organisations in drafting the law. Praising the participants as experts in this field, she asked them to craft a draft that met the following criteria:

- be finalised as quickly as possible
- be a facilitator of research and development of biotechnology
- consider the monitoring aspect of biosafety according to the CPB
- empower the government with sufficient information *vis-à-vis* biotechnological activities in the country

These statements show that potential imports were not at the centre of concerns and of the biosafety law, at least for the DoE at this stage. However, the data on the next stages of negotiations also confirm that there were no disputes over imports and the necessity of checking and testing imported crops, nor were there discussions about how Iran should conduct this process.

Three intriguing disputes provide the context from which I shall elicit three sets of framing assumptions:[57] 1) an unexpected debate over the opening clauses of the law, which lasted nearly two hours, while the head of office had initially suggested eliminating discussion of this part; 2) an emergent challenge between the MoS and the MoH on one side and the MoA, the MoFA and the DoE on the other regarding the differences between field trials and experimental releases, which took more than one and a half hours, a topic that the head of the office had asked be discussed in one minute; and 3) the controversies over the location of the office of the secretariat, which lasted half a day and finally ended with clashes between members precluding any agreement.

As I mentioned earlier in my analytical framework, it could have been expected that the members would differently envisage the policy problems, the risk system (including the risk-generating system and scope of risks) and other causalities within this system as well as policy prescriptions for addressing problems according to their different framing assumptions. The result of the analysis of this stage of negotiations reveals that, with

[57] As I stated in my methodology, I used the suggestion of Levidow et al (1997) that framing assumptions could probably be found in the highly contested disputes.

respect to the above three elements of policy making, members held substantially diverse sets of framing assumptions, as set out below.

5.3.1. Safety or harm in biotechnology as an assumption in defining the policy problem

Contrasting the principal assumptions with regard to the safety or harm of biotechnology generated two entirely different views towards the policy problem. On one hand, there was a view proposing that biotechnology should be considered as safe unless evidence of harm emerged. The supporters of this view were the MoH and the MoS. On the other hand, the DoE held the view that biotechnology should be considered harmful and that for each GM crop, proof of safety would be necessary before authorisation. For the former (i.e. MoS and MoH), biotechnology was considered like other technologies that might pose some risks and harm, while for the latter (i.e. DoE) biotechnology was basically seen a hazard. The data on the view of the MoA were not sufficient at this stage.

These assumptions to a large extent shaped the perceptions of the antagonists over the policy problem that needed to be addressed by the biosafety law. Considering biotechnology as a source of harm or perceiving it as a normal form of technology largely affected the understanding of the protagonists of the problems that needed to be addressed by the biosafety law. In this sense, for the DoE the policy problem was biotechnology itself, while for the MoS and the MoH, the problem was essentially biotechnology development, considering its possible negative effects.

This could explain why the MoH complained about the opening clauses of the draft, although it was not a part of the formal law, arguing: "the current opening clauses give a sense of restriction and fear of biotechnology. This needs to be changed by referring not only to the national biotechnology plan, but also to the importance of biotechnology development for the country, as well as the other achievements of this field." [58]

The MoS endorsed the view of the MoH, suggesting that there was a need to emphasise the importance of biotechnology development, particularly stressing its important position in National Development Programmes such as the five year plan of the country.

[58] Official voice recordings. morning session of the first day of the two-day gathering (author's translation).

Moreover, this Ministry condemned talking much about possible hazards in the opening statements of the draft because "it produces a sense that biotechnology is harmful, while this technology is not harmful in itself. 'Hazards' should be replaced by 'possible risks' that might arise from reproduction or release of modified organisms."[59]

On the other hand, the DoE stressed that the duty of the current committee was the development of a draft biosafety law, not the development of biotechnology. For the DoE, the essential element of the introduction to the draft was to highlight the importance of a precautionary approach as a general principle for confronting possible hazards.

The statements quoted above convey important indications about the framing assumptions of those organisations. On one hand, MoH and MoS argued that biotechnology is not essentially hazardous; therefore the draft should not take hazards, problems and precautions seriously. Instead, the opening clauses should emphasise the importance of biotechnology as a vital technology for development and the progress of nation. In contrast, the view of DoE was characterised by fears of biotechnology as something that engenders hazards, and the idea that biosafety is necessary in order to minimise these hazards.

Members did not, however, spend considerable time discussing those assumptions about biotechnology, notwithstanding the fact that they held entirely different assumptions. They occasionally came across this issue in their discussions to argue whether biotechnology is safe or hazardous, but they did not directly debate the topic. A noteworthy instance in the two-day gathering was when the members were talking about objectives of the law; a biotechnological expert who was not representing any organisation but was participating as a guest, objected: "the statements all bear a negative sense about biotechnology. It is like there is a hazard there and we all are trying to fight this hazard."[60] The MoFA replied: "this is because it is not still proven that biotechnology is safe."[61]

[59] Ibid
[60] Ibid
[61] Ibid

Whereupon the MoS exclaimed: "also it is not yet proven that it is harmful."[62] This disagreement provoked laughter among the other members and remained unresolved.

However, presuming biotechnology is something hazardous or something that might bear risks would have substantial impacts on the perceptions of the policy problem and thus the general approach of the biosafety law. As that expert mentioned, "is biotechnology something negative we are going to fight with, or it is something positive we are going to use in a secure way?"[63] Referring to the contrasting views above, if biotechnology is hazardous, this would be the problem itself, while if biotechnology is something beneficial associated with occasional possible risks, the problem would be identifying and addressing those risks, not confronting biotechnology more generally. Moreover, these assumptions about biotechnology have important implications for the implementation of the law and the required evidence, which I will turn to in later chapters.

5.3.2. Risk system: are research and researchers part of a risk-generating system?

Including or excluding research activities as a part of the system that might generate risk was also a topic for controversies that reflected different views amongst the antagonists about the risk-generating system. In this respect, the MoS and the MoH shared the assumption that research would not be a source of risk as researchers would take sufficient protective measures. On the other hand, the DoE and the MoA were immensely concerned about the possible risks that might arise in the process of research.

The MoS argued that researchers should be able to bring their scientific experiments to the level of farms free from biosafety regulation, as this stage of research aims to explore the characteristics of the modified organisms aside from their interaction with the environment. For instance, a researcher may need to plant 300 lines of variety of crops to find out which one satisfies his desired characteristic. For the MoS, a field trial was a type of research within which the researcher should be free to undertake experiments on various lines to find out which ones work. At that stage, the researcher has no products to sell or distribute. Observing interaction with the environment is an activity that should be

[62] Ibid
[63] Ibid

done for successful lines at a later stage. The MoH also supported this view by portraying researchers as the best people to know how to safely carry out their research.

On the opposing side, however, the MoA warned that 'field trials' are a type of product release because there is the possibility of transferring genes into the environment. Therefore, an examination of the characteristics of the crop needs to be performed in a contained environment to permit the control of relevant variables; otherwise, interaction and gene flow might occur in the experimental phases that in turn might pose substantial problems and even harm. The MoA stressed that research activities could be a source of risk, especially if the researchers failed to provide satisfactory safety measures in their work. On this basis, the MoA felt that the biosafety law should be clear about research activities by clarifying the requirements of the research. The DoE also backed the view of the MoA by pointing to the possibilities of gene transfer and consequent problems that might arise during research.

This debate had also occurred, though to a lesser extent, in the sixth session of the CC. When the MoH asked for an exemption of research from the law, the MoA pointed to the problems that might arise in the process of research. For the MoA, there was no basis for trusting researchers because the quality of research could not be guaranteed all over the country. The representative of MoA revealed his concern particularly for research that might be undertaken in low-quality labs, for instance those that are located in poor universities, as a possible important source of risk. However, the MoH claimed that there would be no problem as laboratories maintain certain safety levels (levels 1 to 3), and safety personnel always check these requirements.

In short, substantial controversies over whether or not research needed to be covered by the law were associated with a central assumption: *whether the law should be drafted based on an assumption of trust of research activities, or whether it should be written presuming research to be a source of potential risk.* In the next chapter, I will discuss this issue in more detail in the light of new data from the second stage of negotiations.

5.3.3. The roles and responsibilities of biotechnology experts in policy prescription

Different suggestions of ways of dealing with and addressing the policy problem, as the third element of my framework, point to a sharp distinction between the framing assumptions of the members, which was manifested in a debate over the proper role of biotechnological experts in different activities pertaining to biosafety regulation and aimed at avoiding or resolving policy problems. Different views of the protagonists over this issue were impregnated with various framing assumptions, including the sufficiency of biotechnology science in answering all risk policy problems as well as the neutrality of their judgments and opinions. These two assumptions are the ones I used to distinguish between the technocracy, decisionism and co-evolutionary models in Chapter 3.

In the case of Iran, the debates over the role of science were reflected in debates over the role of biotechnology experts in the process of legislation and implementation. These could be classified in terms of: 1) the extent to which biotechnological experts should play a role in drafting the biosafety law; 2) the extent of the role of biotechnological experts in setting standards, like standards of handling GMO transportation; 3) the role of biotechnological experts in implementing the law and in risk assessment and risk management; 4) the role of experts in enforcing the law to make sure it is properly obeyed; and 5) the role of experts in making overall policies of the country with respect to biosafety (as members of the NBC).

Linked to this categorisation, another important set of framing assumptions concerned the extent to which the protagonists believed in the necessity of a separation between promotional roles and regulatory responsibilities, including the five roles mentioned above. It is worth noting here that according to the institutionalisation of biotechnology in Iran that was described in Chapter 2, the biotechnological experts of the MoA, the MoS and the MoH were among the few eligible experts who could contribute to the risk assessment, but were also the people who were involved in promotional activities.

In the view of the DoE, having authority over the office of the secretariat was perceived to be the critical feature of biosafety regulation. An indication of this perceived importance

can be found in the statements of the representative of this department in the two-day gathering, such as: "in our view, all biosafety is about the location of the office of the secretariat, what was the root of many disputes in the past."[64]

The DoE placed critical importance on the separation of promotional activities (which are done in other Ministries) and regulatory responsibilities. On this basis, the DoE stated: "the controlling dimension of biosafety is very clear. This department is not involved in biotechnology development and therefore should be the responsible organisation for biosafety to monitor and control biotechnology. Thus, the office of the secretariat must be in the DoE."[65] The interpretation of these comments could be that the DoE conceived biosafety as controlling biotechnology activities, a task that needed to be removed from the organisations working on biotechnology development, and located in a body with environmental protection high on its agenda.

On this basis, the DoE did not agree with the suggestion that other Ministries should be involved in the authorisation of releases. Their view on this topic is reflected in a document prepared by the office after the two-day gathering. In the section about responsibilities, the document summarised the view of the DoE as: "the office should be the only Competent National Authority (CNA) to receive all requests, and, if necessary, send them to other Ministries to get their advice and finally issue authorisation."[66] That is to say, the role of biotechnological experts and their biotech research centres in other Ministries was perceived by the DoE as merely having a role as advisors to come into play at the discretion of the office. Another ramification of this view is that it implies a complete separation between organizations with promotional responsibilities, which could provide advice for risk assessment, and the regulatory jobs such as authorisation and enforcing the law.

Incorporating biotechnological experts into the process of drafting the law could be a sign that the DoE perceived a role for them in this area, because the DoE initiated the CC sessions by inviting senior representatives of other Ministries. An alternative explanation could be that the DoE had not thought out its position in advance of convening the CC.

[64] Official voice recordings. morning session of the second day of two-day gathering (author's translation).
[65] Ibid
[66] See footnote 54.

The documentation also suggests that in the view of the DoE, biotechnological experts should have nothing to do with determining overall policies of the country to become part of the NBC.

The MoH held a view very close to the technocratic model, although it might not be characterised entirely as technocratic view. For this Ministry, not only drafting the biosafety law but also implementing the law and making proper policies for biosafety fell within the territory of biotechnology science. On the first day of the two-day gathering, this Ministry stressed: "because the field of biosafety is essentially sophisticated, regulations have to be drafted by modern biotechnology experts."[67] Further, on the subject of who should take the leading role with respect to implementing the law, the MoH emphasised the central role of biotechnological experts in a letter to the office of the secretariat on 13 August 2006, before the two-day gathering. In one paragraph, the letter underlined the essential role of biotechnological experts and in another paragraph, it argued that all implementation and management duties should be delegated to these experts, stating that: "operational activities in relation to management, control, monitoring and assessment in principle should obviously be carried out by Ministerial committees because of their expertise in this area, and hence they should be considered Competent National Authorities (CNA)."[68] This Ministry endorsed the suggestion that even the NBC should incorporate some biotechnological experts into its composition. As a result, for this Ministry there was no need to consider any separation or conflict between bodies with promotional responsibilities and those with regulatory responsibilities.[69]

Available documents suggest that the MoS, much like the MoH, held a model very close to the technocratic model at that stage of negotiations in considering an ultimate role for biotechnological experts at different stages of decision making. There is a document from the office which summarises the opinions of the MoS at the start of the CC sessions.[70] In

[67] Official voice recordings. morning of the first day of the two-day gathering (author's translation).
[68] MoH, letter to the head of the office of the secretariat in DoE, no. 4076, 13 August 2006.
[69] The MoH emphasised this point in two separate letters, both issued on 13 August 2006, one to the head of the office in the DoE and one to the head of the DoE. The latter letter's number was 162712. Sending these two letters on the same day indicated similar points; while the first one was signed by the Minister of Health and the second one by the head of the Pasteur Institute (PI) of Iran, it shows how important this issue was for the MoH.
[70] I have a copy of this document titled "The opinions of MoS before the gathering". This means that the office summarised the suggestions of this Ministry before starting the two-day gathering.

terms of identifying the members of the NBC, the MoS suggested adding three outstanding biotechnological experts as well as the representative of the biosafety society of Iran as a scientific community to provide sound scientific information for other members of the NBC, which could be composed of relevant Ministers as well as the President or the First Deputy. This shows that in the view of this Ministry, biotechnology scientists should play an important role in national policy-making, though they could not be given the full authority to do this job.

With respect to implementing the law, the MoS stressed several times that decisions about research activities should not be included under biosafety, unless the researchers want to release a product. The MoS suggested that the law should empower the CC as the body that takes decisions over the release of GM products, which would encompass a mix of scientific representatives of Ministries involved in the promotion of biotechnology and representatives of other Ministries and organisations that might not be experts in the field. Incorporating biotechnology science at all stages of decision making denotes that for the MoS, the separation between promotional responsibilities and regulatory responsibilities was not necessary, yet the MoS strongly supported the view that biotechnological scientists should be present at all stages of decision making.

The view of the MoA resembles a type of Weberian decisionist policy making model, which on one hand emphasises the necessity of having scientific experts in implementation and on the other hand calls for goal setting by politicians. On this basis, the MoA stressed that the implementation of the law, including authorisation, risk assessment and even managing the risk should be carried out by the expert organisations, while the general policies of the country and specific decisions should be delegated to the NBC as a political body. In other words, politicians set the biosafety policies and goals while experts implement them.

Together with the MoS and the MoH, the MoA also condemned the lack of sufficient knowledge and expertise in the DoE as a factor that might pose substantial problems in the way of biosafety. The MoA strongly supported the idea that experts should take the leading role in implementing the law as well as contributing to drafting the law. A

document prepared by the DoE after the two-day gathering summarising the views of organisations and Ministries reveals more about the views of the MoA.[71] In terms of authorisation, the document states that the MoA suggested the authorisation should be done by the MoA and the MoH as two expert organisations that should also be the only CNAs. This means that for the MoA, implementing the law and making decisions under provisions of the law was seen an activity that had most to do with expertise rather than politics. This could also explain the concerns of the MoA from the outset about the shortage of scientific knowledge in the DoE as the location of the office of the secretariat.

On the issue of general policies for biosafety, the MoA repeatedly stressed that it was a political responsibility that should be separated from scientific judgments.[72] In other words, while biotechnology experts should be involved in the process of implementing the law through assessing and managing the risks, the overall policies of the country are a subject scientific expertise cannot decide. Therefore, the NBC should be composed of people with political responsibilities rather than biotechnological experts or scientific representatives of Ministries and organisations.

5.4. Discussion of the Results

This chapter has reviewed the first stage of the legislative negotiations to find out the possible underlying framing assumptions of organisations and Ministries about policy problems, the risk system and prescriptions for addressing those problems. The available data has revealed that some different and even contradictory framing assumptions between organisations and Ministries underpinned their entirely different approaches. In this section, I will integrate the findings into a table (Table 5-1) and will then discuss how those assumptions were discussed in the literature of technological risk regulation.

5.4.1. Summary of the Findings

Table 5-1 shows the major themes on which the DoE and the MoH, the MoS and the MoA held different, and to some extent contradictory, framing assumptions at this stage of negotiations. A pivotal problem arises regarding the assumptions over safety or harm in

[71] See footnote 51.
[72] Official voice recordings of the sessions. Session 5 of CC and the first day of the two-days gathering (Author's translation).

biotechnology: is it assumed to be safe until proven hazardous, or assumed to pose risks until proven safe? This assumption largely affects the definition of the problem, as in the former understanding, the problem would be biotechnology itself, whereas in the latter the problem would merely be considering the possible risks that might arise from development and application of biotechnology. This pivotal issue highlighted a distinction between the MoH and the MoS on one hand and the DoE on the other hand, while the position of the MoA was not clear at this stage.

Presuming the research activities of scientists as a part of the risk system that might generate risks shapes a sharp distinction between two groups: 1) the MoH and the MoS, which were suggesting that the law should trust scientific research, and 2) the MoA and the DoE, which were arguing that the process of research may also be characterised by risks that in turn might pose harm to the environment or to human health, and therefore the law should cover all research activities.

Table 5- 1 Divergent framing assumptions of Ministries and organisations at the time of the CC and the two-day gathering

Elements of Framing	Contested Issues	MoH	MoS	MoA	DoE
Assumptions affecting understandings of the nature of policy problems	*Presuming biotechnology safe or harmful?*	Framing Assumptions			
		Presuming biotechnology is safe unless there is proof of harm.	Presuming biotechnology is safe unless there is proof of harm.	[Lack of data for the first stage of negotiations]	Presuming biotechnology is a harmful innovation if there is no proof of safety.
Assumptions regarding the risk system	*Research activities as a source of possible risk?*	No. Researchers are the best people to ensure the safety of their work.	No. Research activities will not generate risks.	Yes. Researchers might fail to put in place safety measures and therefore impose substantial risks.	Yes. Research activities as a part of the risk-generating system.
Assumptions about ways of dealing with the problem (e.g. models of risk assessment and risk management)	*Role of biotechnological experts in the process of regulation?*	• Only biotechnological scientists should draft the biosafety law • Only biotechnological scientists should implement the law • Biotechnological scientists play a decisive role in general biosafety policy-making	• Biotechnological scientists should contribute to drafting the biosafety law • Only biotechnological scientists should implement the law before releasing products • Biotechnological scientists and policy-makers should decide together over releases • Biotechnological scientists should play a decisive role in general biosafety policy-making	• Biotechnological scientists should be incorporated in the drafting • Only biotechnological scientists should implement the law • Biotechnology scientists should not be involved in general biosafety policy	• Biotechnological scientists could be incorporated in the drafting • Biotechnological scientists should not take part in implementation and enforcement • Biotechnological scientists should not be involved in general biosafety policy
	Separation of promotional from regulatory responsibilities?	No need for separation at all	No need for separation at all	• No separation between promotion and implementation • Separation between policy and implementation	• Separation in that there is no role for biotechnological science in implementing, or enforcing policy

With respect to the role of biotechnological experts, however, the diversity of views among the members is greater. Although for both the MoH and the MoS biotechnological science should be incorporated into the stages from drafting to implementation and even involved in making general policies, the MoH presumed that drafting and implementing the law was purely a scientific job to be done by biotechnological experts, which in turn suggests a purely technocratic view according to which science could objectively solve all relevant policy problems. For the MoS, biotechnological experts in cooperation with other authorities should draft and implement the law, which differentiates its view from a pure technocracy. The MoA suggested that the process of implementing the law should be purely a task for experts; on the other hand, this Ministry envisaged no place for scientists in the process of determining overall biosafety policies and therefore it presupposed a separation of science from politics by locating scientists in the implementation stage and politicians in general policy making, which resembles a decisionist model. Finally, the DoE accepted a role for biotechnological scientists in participating in drafting the law, while it was strongly opposed to giving them any role in implementing or enforcing the law.

Overall, the approach of the MoH could be characterised as a view that not only accepted the promotion of biotechnology and research, but also assigned a vital role to biotechnological scientists in the regulation of biotechnology. Although the MoS also supported the notions of promotion and research, its approach was not as the same as the MoH with regard to the exclusive role of biotechnological experts at all stages of decision making. The view of the MoA over the safety of biotechnology was not clear at this stage, though this Ministry was seriously concerned that research activities could be a source of risk. The MoA also supported the idea that implementing the law would be a scientific task, although not just involving biotechnology science, while at the same time it maintained a sharp distinction between the political decision-making of the NBC and the implementation of the law by expert organisations. Serious concerns of the DoE over the safety of biotechnology along with worries about research activities as a part of the risk-generating system were coupled with its view that biotechnology scientists should have no

role in implementing the law; it envisaged a sharp separation between promotional and regulatory responsibilities.

5.4.2. Identified assumptions in the literature

In my theoretical framework in Chapter 4, I listed several academic works discussing framing assumptions in regulating biotechnological risk that may be useful here. The above table, although it is an initial finding for the first stage of negotiations, contains some notions that are very close to the assumptions identified by the risk regulation literature. The first principal issue about biotechnology was reflected in Millstone et al (2004) in their discussion of symmetry of the required data. They describe a type of symmetry as to whether or not GM crops are assumed risky unless shown to be safe, or assumed safe unless shown to be harmful.

In terms of the risk-generating system and the question of whether risks can arise from research activities, this notion is very close to Jasanoff's (1995, 2005) formulation of biotechnology as a product or process. Jasanoff highlighted the differences between the USA and the UK in their different views over regulating biotechnology as a product, as a process or as both. However, my framework implies that biotechnology as a product or a process could be understood in relation to the risk system, in that part of it accounts for generating risks, and whether biotechnology products constitute this system or whether the processes of biotechnology development should also be counted as a part of this system. The evidence shows that for the MoH and the MoS biotechnology research processes were not a matter of risk generation, while for the MoA and the DoE those processes might engender risks and harm.

5.5. An account of the policy output

This stage of policy making ended with clashes between organisations, and without any clear results. To understand changes to policy in later stages of the negotiations, it would be helpful to discuss the output of the two-day gathering to clarify how the members agreed to leave the session without any clear decisions. For this purpose, I will take a

closer look at the efforts of the members and the circumstances in which the members decided to end the discussions.

The sequence of events through which members disputed on the location of the office could be summarised as:[73]

1- The MoA, the MoH and the MoS disagreed with locating the office in the DoE, arguing that it lacked expertise and knowledge. Another group, namely the DoE, the MoI and the MoFA agreed to delegate the office of the secretariat for the NBC to the DoE.
2- The former group suggested not identifying the location of the office in the law, but leaving it within the authority of the NBC. This suggestion was rejected by the second group.
3- As another resolution, the first group (i.e. MoH, MoS and MoA) offered to write notes of disagreements in brackets to signify that the session could not reach a clear decision. That offer was refused by the second group.
4- The head of the office of the secretariat of the NBC (who was also the representative of the DoE) left the session at lunchtime to talk and consult with the head of the DoE. However, what he then reported in the afternoon on behalf of the head of the DoE was rejected by the MoS, the MoH and the MoA. The second group argued that the opinions of the DoE were not acceptable to their affiliated Ministries.
5- The DoE and the MoFA suggested diminishing the presumed responsibilities for the NBC office and delegating more responsibilities to other Ministries. The second group (i.e. MoA, MoS and MoH) replied that they would accept this idea just as long as their Ministries were recognised as the CNAs which could authorise relevant categories of products.
6- The MoT proposed writing the disagreements in a covering letter rather than stating them in the text of the draft. The MoH, the MoS and the MoA rejected that suggestion.

[73] Official voice recordings of the second day of the two-day gathering.

7- The MoS suggested using a voting system as a last resort. However, a problem emerged with respect to the order in which the suggestions would be brought to the vote, i.e. firstly voting on the bracket and then, if it failed, moving to the next idea or to other alternatives. The members could not reach an agreement in this respect and therefore voting did not proceed.
8- Eventually, the session ended without any agreement or result.

Looking back at this journey, a common characteristic is that repeatedly one group or a few members were able to resist the suggestions of other groups or members. It resembles a system within which power is equally distributed: all members were on a par with each other, while the decisions needed to be consensual. Therefore, regarding the policy output at this stage, and given the fact that no organisation had sufficient power to impose its opinion, it is possible to conjecture that the contradictory position of the framing assumptions of members could account for the lack of an output at that stage. On this basis, an interesting topic for the next section is analysing the change to this output, which was a draft biosafety law, to find out how that output was achieved. Did the members change their framing assumptions? Could some of them not resist the arguments and criticisms, leading to a paradigmatic change, or did the power relations change? In the next chapter I will discuss the NBC session and the RC as the subsequent efforts for developing a draft.

Chapter 6. The Second Phase of Negotiations: National Biosafety Committee and Reviewing Committee, December 2006-May 2007

6.1. Introduction

After the failure of the CC to produce a draft biosafety law, the head of the DoE tried to solve the problem in a different way. As the office of the secretariat of the NBC, the DoE arranged a session of this committee involving the related Ministers and the first Deputy President to find a political resolution. However, the problem was not solved by that NBC session and the members continued discussions over the draft in a new round of negotiations. This was called the Reviewing Committee (RC) and consisted of eight sessions. For the RC sessions, the head of the DoE changed the participants by inviting Deputy Ministers rather than their senior biotechnology representatives to pursue a political approach. Eventually, as a result of the RC sessions, a draft biosafety law was passed to the NBC.

In this chapter, I will discuss the NBC session as well as the RC sessions as a separate policy process, and examine the way it generated an output in the form of a draft biosafety law. The main concerns of this chapter are: did the framing assumptions, which in part were identified in the previous chapter, emerge again in this stage of negotiations? If so, did they change and if they did, to what extent and why? Did the new data, with respect to this stage, lead to new framing assumptions? Are they related to the output of this stage of the policy process, and if so, how? To what extent do the framings and their changes contribute to understanding the new policy output?

6.2. National Biosafety Committee Session

The NBC session was held on 14 December 2006 and was attended by the following: the first Deputy President, the Minister of Agriculture and his Deputy, the head of the DoE and one of her Deputies, the Deputy Minister of Health, and the Deputy Minister of Science. In addition, the head of the office of the secretariat, who was the senior representative of the DoE, as well as the representatives of the MoH, the MoS and the MoA in the CC negotiations were present in this session.

The head of the DoE started the session by pointing to the main problems, as she saw them, which had arisen in the earlier policy process (i.e. the CC). Intriguingly, she stressed that there was no disagreement with respect to the initial parts of the draft, including its opening clauses, definitions, objectives, and the scope of the law.[74] In fact, those were the only topics that could be discussed at the two-day gathering. The head of the DoE pretended, or perhaps believed, that there were no problems regarding those topics, while the analysis in the former chapter contradicts this view and argues that the members of the CC held different framing assumptions, especially with regard to the opening clauses of the draft as well as scope of the law.

In the head of the DoE's view, the main problem arose in the suggested structure for implementing the law, especially *vis-à-vis* two important topics: 1) identifying the Competent National Authorities (CNAs) that would have the authority to issue or cancel authorisations, and 2) the location of the office of the secretariat and whether the location needed to be determined by the law. The head of the DoE optimistically claimed that if the NBC session could find a solution to those problems, the other parts of the draft could be finalised very soon.

Referring to the framing assumptions identified in the previous chapter, the statement of the head of the DoE at the beginning of the NBC showed how she had not acknowledged the main points of disagreement over the framing assumptions. In fact, she represented the problem as something that merely had to do with implementation and allocating responsibilities. Further, by considering this view of the DoE, we might better understand why the head of the DoE convened the NBC session to deal with this problem: in principle, she was seeking a resolution and a decision from the political authorities to settle a division of responsibilities, without addressing several contested framing assumptions, such as those that incorporate the problem definition and competing understandings of the risk system.

The reaction of the Minister of Agriculture to the head of the DoE's speech may have undermined the latter's expectations. The Minister of Agriculture argued that the former

[74] Official voice recordings of the NBC session held on 14 December 2006 (author's translation).

decision of the MoA to agree with the shift of the office to the DoE at the beginning of 2006 was mainly aimed at reducing tensions. He continued: "the performance of the DoE was so weak that the MoA regrets that decision."[75] The other members then put forward their opinions and finally the Deputy President suggested some principles as a basis for rewriting the draft in further sessions, which were called the RC sessions.

Notwithstanding the fact that two hours in a political session was not sufficient for the members to present their full viewpoints, some interesting points were raised *vis-à-vis* framing assumptions that can be added to the framing assumptions identified in the last chapter. I shall continue the discussion by asking if there is any evidence in the speeches of the members of the NBC that might enhance our understanding of their framing assumptions. Moreover, were there further signs of new framing assumptions?

6.2.1. Safety and harm of biotechnology in defining the policy problem

Safety or harm of biotechnology was identified in the last chapter as an important underlying framing assumption that strongly influenced the understandings of general policy problems that should be addressed by biosafety law. In the NBC session, new points appeared that help enrich this picture.

The senior representative of the MoA pointed out that the MoA was currently authorising varieties of agricultural crops and goods and it could do the same for GM products. He argued that a GMO is not a distinctive category; instead, it is something familiar that has just been manipulated. He characterised the process of manipulation not as something unusual, insisting that biotechnology is not different from other familiar technologies such as traditional plant breeding. Although he did not reveal much about to what extent he expected biotechnology to be safe or harmful, he portrayed biotechnology as more or less similar to other technologies, which might signify that for the MoA biotechnology might not be seen as hazardous, or as no more hazardous than familiar plant-breeding methods.[76]

[75] Ibid
[76] Official voice recordings of the NBC session held on 14 December 2006 (author's translation).

The Deputy DoE defended their approach by saying: "there is a missing point *vis-à-vis* the goals of biosafety. It is for maintaining the biodiversity of the environment in its current form, as a whole and integrated entity in the world and through restricting manipulation by humans. It is about not changing God's creation."[77] This statement conveys a view that biotechnology was perceived by the DoE as manipulating the creations of God. This notion refines the previously-identified negative view of the DoE towards biotechnology: something that is, at least, often threatening.[78]

The senior representative of the MoS revealed much about the approach of that Ministry. He said: "there are two views of biosafety: 1) biotechnology is harmful and biosafety seeks to find ways for preventing harm by hindering the development and use of biotechnology, and 2) biotechnology is beneficial, but might confer some risks, like other technologies. The MoS believes in the second approach."[79] This statement is very illuminating because it not only clarifies the position of the MoS with regard to harm and safety in biotechnology, but also shows that the MoS was aware of the presence of such conflicting views towards biotechnology. Nevertheless, this issue was not subsequently discussed.

6.2.2. The risk system

The analysis in the previous chapter suggests that there were differences between the protagonists in terms of their assumptions towards the risk system, including the risk-generating system, as well scope of those risks. The data for this phase of negotiations indicate two sets of framing assumptions: 1) assumptions about the risk-generating system as part of the risk system, and 2) assumptions about the scope of the risks and the border of causalities within the system.

6.2.2.1.Risk-generation and the role of research activities

The previous findings suggest that part of the disagreement stemmed from diverse understandings of the extent to which research activities might be a source of risks, and

[77] Ibid
[78] There is little evidence pointing to the popularity of this view in the DoE. Therefore, I prefer to take the side of caution with respect to attributing an absolute anti-biotechnology view to this department rooted in a religious assumption.
[79] Official voice recordings of the NBC session held on 14 December 2006 (author's translation).

therefore whether or not the law should trust research activities. In this respect, the representative of the MoA proposed that identifying GM products[80] and their risks would not need a separate biosafety law. He argued: "enacting the biosafety law as a new law becomes especially important because Iran is going to develop and make progress in biotechnology, and as this process confers both positive and negative sides, there is a need for a law to deal with the process and reduce the possible risks coming from it." [81] These ideas show that in the view of the MoA, development activities and processes were counted as a part of the risk-generating-system, which in turn called for a biosafety law and implied that research activities needed to be included in the scope of that biosafety law.

In clear oppositions, both the MoH and the MoS argued for an exemption of research activities, emphasising the restrictive nature of the DoE's approach as well as the essential role of research in biotechnology development and the progress of the country. However, the members never discussed whether or not risks might arise during research.

6.2.2.2. Scope of the risks as part of the perceived impact within the risk system

Different perceptions about the scope of risks shaped another part of the different views about the risk system and referred to the border of impacts and causalities within the system (scope of risks). Discussions in the NBC session revealed another difference in those respects.

The Deputy of the MoA revealed a new notion about the scope of risk. He repeatedly emphasised the importance of having a law that would fill the current gaps in Iranian law. Pointing to the intricacy of developing a law to meet international commitments as well as internal needs, he highlighted a widespread concern in the MoA arising from the lack of a biosafety law. The Deputy of the MoA admitted that the non-existence of a biosafety law was itself a political risk to Iran, as several other countries had already asked Iran to provide certificates indicating that its exported products were GM-free (e.g. tomatoes and pistachios). This was mainly because Iran and those trading partners had joined the CPB

[80] As opposed to the process of developing biotechnology
[81] Official voice recordings of the NBC session held on 14 December 2006 (author's translation).

and therefore had mutual obligations. For this reason, there was a need to compromise between different approaches for the sake of enacting a law as soon as possible to address the external political risks.[82] In this sense, in the view of the MoA, the risks were not just physical risks to be discussed in terms of human health and environmental issues, but also included the political risks that might come from the lack of a biosafety law.

6.2.3. Policy prescriptions and the role of biotechnological experts

The head of the DoE revealed a great deal about the approach of her organisation by claiming that the critical feature of biosafety regulation is control of biotechnology to protect biodiversity, and that therefore responsibility for regulation should be separated from responsibility for biotechnology promotion. Moreover, because the DoE would not benefit from applying this technology, it felt that it was best placed to carry out regulation. These statements make it clear that, in the view of this department, there must be a sharp distinction between regulation and promotion. On this basis, the DoE argued that the office of the secretariat of the NBC should be in the DoE as the sole CNA.[83]

These arguments also suggest that the DoE was suspicious of those actively trying to promote biotechnology, either agricultural or pharmaceutical. In emphasising that the department would not benefit, the DoE implicitly suggested that the people who could benefit from biotechnology might be influenced by their interests and values in decision-making, and consequently were not suitable institutions for controlling biotechnology as a critical part of regulation. Further, these statements help us to better understand the concerns of the department over research activities as a part of the risk-generating system, as researchers might not always provide sufficient safety measures in their work when pursuing their own economic and technological interests.

These concerns led the DoE to emphasise the necessity of imposing severe penalties and prosecutions in response to violations, to balance benefit-seeking behaviours with possible negative consequences. Hence, in the view of this department, biosafety regulation should be responsible for controlling and monitoring biotechnological activities as a disinterested

[82] Official voice recordings of the NBC session held on 14 December 2006 (author's translation).
[83] Ibid.

organisation with the power to impose penalties over contraventions. This could also explain why the head of the DoE chose a non-biotechnological expert as the head of the office of the secretariat to make sure that he would not pursue biotechnological interests.[84]

Both the Minister of Agriculture and his deputy condemned the view of the DoE on the control of biotechnology. Referring to two expert organisations in their Ministry, i.e., the Protecting Plants Organisation, responsible for monitoring all plants, and the Veterinary Organisation, responsible for controlling all meats and animal parts that are being used in the country, they rejected the approach of the DoE by asking how the DoE could accomplish such professional tasks without any expertise in biotechnology. This reveals that in their view experts have very important roles to play in implementing the law. On this basis, the MoA entirely disagreed with the approach of the DoE in having sole responsibility for biosafety. Their emphasis on the necessity of including biotechnology experts in implementing the law might suggest that in their view those experts or expert organisations act independently of vested interests; however the representative of the MoA did not explicitly argue this in the NBC session.

6.3. National Biosafety Committee Output

After two hours listening to the views of organisations and Ministries, the First Deputy President drew some conclusions as a basis for a new draft to be prepared in a session, or multiple sessions, to be held by incorporating the DoE, the MoH, the MoS and the MoA as the four main organisations involved in the issue, and preferably in the presence of the head of the DoE.

The First Deputy President suggested the following guidelines:

1- Ministries and the DoE discharge their mandates without overlapping with the responsibilities of others
2- Exclude research activities in laboratories from the scope of the law

[84] The head of the office was an expert in nanotechnology

3- Responsibility for authorisation to be held by the MoA and the MoH, while the information is to be shared with the office of the secretariat of the NBC
4- The NBC office plays a solely coordinating role
5- International relations to be considered within the responsibilities of the NBC office
6- The NBC office could bring cases of violations to the Coordinating Committee and if they could not reach a decision, NBC should deal with them.

The Deputy of the DoE dissented from the first guideline by arguing that biosafety is different from other fields because it needs a central monitoring institution.[85] He reminded the First Deputy President of a former challenge regarding Avian Flu, about which the First Deputy had proposed a similar guideline that organisations should not overlap with each other. The Deputy DoE added that biosafety is different from Avian Flu, and requires a different approach. The head of the DoE then added that biosafety is for the control of biotechnology and the DoE is the organisation that should be responsible for this task because it will gain no benefit from biotechnology development. Nonetheless, the First Deputy President dismissed the concerns of the DoE and ended the session.

Regarding this policy output, although the members were arguing based on different framing assumptions, there was not a heated debate in that session comprising people with political responsibilities including the First Deputy President. In contrast to the experience of the two-day gathering, which ended with a clash between organisations and Ministries, this time the First Deputy President used his power to overrule the criticisms of the DoE on the one hand, and to dismiss the complaints of other Ministries during the session about the responsibility of the DoE in taking the office of the secretariat on the other. In other words, analysing the experience of the NBC session suggests that the most powerful person in that process used his authority to end the session with some clear outputs by rejecting some views in favour of others and by proposing new actions.

[85] Official voice recordings of the NBC session held on 14 December 2006 (author's translation).

In this sense, while framing assumptions could help account for the positions of the Ministries and organisations during the process and the roots of the controversies, understanding them would not provide an account of the policy output without some understanding of the power relations as well as the framing assumptions. Hypothetically, if there had been sufficient knowledge about the power relations, knowledge of the framing assumptions might have made it possible to anticipate the policy outcomes. However, for the NBC session, there is no knowledge about the framing assumptions of the First Deputy President as the most powerful person.

6.4. Reviewing Committee Sessions

RC negotiations started after the NBC session and continued for eight sessions. When the DoE could not reach a satisfactory solution in the NBC (and perhaps the problem worsened for this department when the First Deputy President rejected any idea of locating all responsibilities for biosafety in one organisation), the head of the DoE invited deputy ministers to come to a meeting on 26 December 2006 (less than a fortnight after the NBC session) to endorse the minutes of that session and use the resulting guidelines as an overall approach, to conclude a draft as soon as possible.

At the beginning of the first session of the RC, the head of the DoE summarised the results of the NBC session as follows:

- Laboratory research was to be exempted from the scope of the law
- There was a need to review other laws and regulations and not cut across them
- The office of the secretariat of the NBC was supposed to take on a coordinating role, although its location was not discussed in the NBC session
- It was undecided who should play the controlling role[86]

The Deputy MoH claimed that another decision of the NBC session had been about the scope of the biosafety law, namely that it should be the same as the scope of the CPB, which meant that pharmaceuticals would be exempted from the scope of the biosafety law. The Deputy MoH claimed that the Deputy President had proposed this in response

[86] Official voice recordings of the first session of the RC on 26 December 2006 (author's translation).

to a question from the MoH after the cassette recorder had been switched off towards the end of the NBC session, while the head of the DoE claimed that she did not hear anything regarding this issue in the NBC session. Ironically, the head of the office of the secretariat located in the DoE supported the MoH, but the head of the DoE remained adamant. After an hour debating the outputs of the NBC session, the members decided at the end of the first meeting of the RC to go through the draft once again and read it paragraph by paragraph to quickly finalise it (hopefully within two sessions, according to the view of the head of the DoE). [87]

These events from the first session of the RC imply two points. First of all, they demonstrate that although the NBC session ended with some guidelines that had been tabled by the First Deputy President, interpretations among the members of the results of that session were different when they discussed them in the first session of the RC. In this session, the head of the DoE summarised one of the conclusions of the NBC session as: no decision had been taken about who should control biotechnological activities. However, according to the analysis of this research, having control over biotechnology was crucial for the DoE and partly for the MoA, while the MoS and the MoH did not see the necessity of this task. In other words, the DoE interpreted at least some results of the NBC session according to its own understanding of biosafety and because of its framing assumptions that biotechnology should be considered risky, and biotechnology scientists might follow their own interests.

Secondly, the members did not have similar ideas with respect to which points had been previously agreed. The example of disputes over whether or not the First Deputy President had suggested setting the scope of the law as similar to the scope of the CPB was a case in point. Further, as I pointed out before in discussing the NBC, some, like the DoE, were not in favour of concluding that the Ministries would take part in implementing the law, i.e. disagreeing over what had been clearly presented as the output of the NBC session by the First Deputy President.

[87] Though it took eight sessions…

As the members agreed to read the draft again and, as a result, to discuss the challenging issues once again, similar to the style of negotiations in the CC, there were plenty of occasions in the RC sessions when protagonists revealed their framing assumptions. In the following sections, based on the data from eight sessions of the RC, I will highlight the framing assumptions that had not arisen in the CC and thus were not discussed in the previous chapter, or those which contribute to a better understanding of the formerly identified framing assumptions.

6.4.1. Safety and harm of biotechnology in relation to the policy problem

There were some comments during the RC sessions which not only confirmed the earlier indications of the framing assumptions about safety and harm of biotechnology, but also suggested a better understanding of the views of the Ministries and the DoE on this topic.

The head of the DoE both in the first and second sessions of the RC revealed her concerns over the safety of biotechnological products by stressing that it should be the responsibility of researchers to prove[88] that their biotechnological products are safe, by providing sufficient and satisfactory scientific evidence. As an example, referring to the Iranian GM rice, she asked how it was possible to make sure it was safe.[89] These comments clearly show that, in the view of the DoE, biotechnological products like the Iranian GM rice were not seen as un-problematically safe. However, she did not specify how much evidence would be sufficient to make the DoE certain with respect to the safety of biotechnological products.[90]

In response to these concerns of the head of the DoE, the representative of the MoH argued that there was no risk from the GM rice because the inserted gene was already present in the environment, especially in the soil.[91] For the MoH, if GM rice was felt not to be safe, it was the responsibility of its opponents to demonstrate that it was harmful to the environment. In the third session of the RC, the Deputy of the MoH complained: "the DoE raises concerns over biotechnology development, which are not legitimate.

[88] 'Prove' was she exact term used (author's translation).
[89] Official voice recordings of the first session of the RC on 26 December 2006 and second session on 2 January 2007 (author's translation).
[90] Also, in principle this was an issue to be decided in drafting the practical rules after passing the law
[91] Official voice recordings of the first session of the RC on 26 December 2006 and second session on 2 January 2007 (author's translation).

There is no basis for worrying about biotechnology development."[92] Also in the first RC session he stressed that "it seems the DoE likes to restrict internal activities mainly because of its own concerns. This is not reasonable."[93] This implied that in the view of the MoH, a modified product that emerged from the process of research would not pose considerable risks.

6.4.2. The risk system

Following the previous findings, the general biosafety system could be divided into two sub-systems: 1) the system that contributes to generating the risk, the issue for the case of Iran being whether or not research activities should be seen as part of this system, and 2) the system that might be affected by those risks, and the border of causalities that defines this system.

6.4.2.1.Research as a part of risk-generating system

The head of the DoE repeatedly revealed her concerns with respect to the developmental activities within the country, mainly arising from a lack of trust in the safety of the research of Iranian scientists. In the first RC session, she drew the attention of the MoH to the fact that even presuming current scientists obey safety rules, what if future generations did not comply with safety measures? Was it possible to leave everything to the scientists? Therefore, there was a need for stringent rules and regulations.[94] In the third RC session she raised a fear about people who might not take safety concerns seriously. The head of the DoE then recommended devising the law in a way to close all possible opportunities for abusing biotechnology.[95] The stress by the head of the DoE on possible problems in future was clearly linked to her assumption that the interest of scientists could be a factor leading them to implement safety measures inadequately that could render the process of research a part of the risk-generating system.

In this respect, the MoA adapted an approach close to that of the DoE by recommending the inclusion of research activities in the scope of the law to prevent possible harmful

[92] Official voice recordings of the third session of the RC on 6 February 2007 (author's translation)
[93] Official voice recordings of the first session of the RC on 26 December 2006 (author's translation)
[94] Ibid.
[95] Official voice recordings of the third session of the RC on 6 February 2007 (author's translation)

mistakes by researchers who would otherwise remain free to undertake any activity they might wish.[96] However, the source of their concerns was different, as the DoE was primarily pointing to the possibilities of abusing biotechnology, while the MoA was primarily concerned with the lack of sufficient experimental equipment and controls in the laboratories or other research fields that could engender harm. In this sense, the MoA was asking research activities to be included as a possible source of risk not because of the same assumption as the DoE, i.e. concerns about the interests of scientists, but because of a concern about the equipment and facilities around the country.

On the other hand, the MoH and the MoS reiterated their former positions on the necessity of trusting research in the law by claiming that no risk would arise during the process of research.

6.4.2.2. Scope of the risk and the causalities within the risk system

The discussions between the MoH and the DoE on the issue of GM rice also provided indications about their different assumptions regarding the scope of the risk. The head of the DoE clearly raised the question that while the GM rice was developed in a way to kill certain target insects, how was it possible to make sure that it would not harm other non-target insects?[97] This question points to the fact that in the view of the DoE, not just target organisms, but also non-target organisms should be included in the scope of risks. In the second RC session, the head of the DoE proposed also considering indirect as well as long-term effects of GM products.[98]

The MoH complained that there was no need to consider indirect and long-term effects, or non-target harm. The assumption that science should be responsible for regulation as the only source of reliable knowledge framed the view of the MoH about the scope of the risks. The Deputy of the MoH argued that the DoE's sorts of concerns were not scientific and therefore not legitimate, and were invoked just to create barriers in the way

[96] Official voice recordings of the second session of the RC on 2 January 2007 and third session on 6 February 2007 (author's translation).
[97] Official voice recordings of the first session of the RC on 26 December 2006 and second session on 2 January 2007 (author's translation).
[98] Official voice recordings of the second session of the RC on 2 January 2007 (author's translation).

of scientific risk assessments.[99] For the MoH, while the issue needed to be handled in a scientific way, concerns about long-term and indirect effects are not the ones scientists can yet legitimately address.[100] In this way, the MoH suggested a narrower scope for the assessment of risks, but also revealed another assumption, namely that the scope of the risk assessment should be decided by scientists, not politicians.

6.4.3. Prescriptions and the role of biotechnology experts

Challenges over the proper roles and responsibilities of biosafety continued in the RC. The DoE reiterated that the pursuit of biosafety entailed that the DoE should be the central player as a monitoring agent, separate from pursuing benefits from biotechnology. Nonetheless, there was a change in the approach of this organisation with respect to two issues. Firstly, changing the structure of negotiations by inviting the deputies of Ministers and giving no role to the biotechnological experts in the discussions about drafting the law was a sign that, in the view of the DoE, those experts should not even participate in drafting the biosafety law, or at least would not be able to help in drafting a law, although they had had a role as the senior representatives of Ministries in the former CC negotiations. Moreover, the DoE further proposed to the RC that the biosafety law should even indicate that the post-law CC[101] should be composed from the deputy ministers, not the representatives of the involved ministries who might be biotechnological experts.[102] (A post-law CC was suggested by some members as another part of the biosafety structure to set operational rules and procedures of risk assessment and risk management as well further administrative tasks.) The MoS rejected this idea by referring to the fact that the responsibilities of the CC would mainly be setting the standards and rules. In the view of the MoS, these jobs were appropriate for experts, not Deputy Ministers. However, the head of the DoE dismissed this idea by replying that the Deputies Ministers could consult experts. This suggests that the DoE was trying to preclude any decisive role for biotechnological experts, even in setting the standards.[103]

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[99] The deputy of the MoH repeated the same argument in the interview session.
[100] This idea resembles the seminal work of Weinberg (1972) who coined the notion of trans-scientific matters: the issue of facts that could be asked by science, but could not be answered by science
[101] While the CC had worked on drafting the law, the members had discussed whether or not there should be such a committee after passage of the law and if so, with what responsibilities and composition.
[102] Official voice recordings of the fourth session of the RC on 26 December. 2006 (author's translation).
[103] Ibid. Indeed the disagreement between the MoS and the DoE over the composition of the post-law CC was among the hottest debates of the RC.

Secondly, while the first Deputy President had suggested that the MoA and the MoH should be involved in the process of implementing the law, such as authorising products for release, the negative view of the DoE of the inclusion of those bodies with promotional responsibilities was evident. The head of the DoE argued that the RC should write the law presuming that the bodies who were supposed to implement the law might not follow the rules of biosafety; therefore, the biosafety law should be written strongly enough to provide assurance on those issues as well.[104] She repeated this view in the next session, arguing that if in the future the organisations involved in the implementation of biosafety tried to act solely according to their own promotional interests, the law should be able to prevent them.[105] That is to say, while the DoE was concerned about the interests and benefits of bodies involved in the process of promoting biotechnology; it was therefore worried about delegating a role to those Ministries with respect to implementing the law.

On the other hand, the MoA pointed to the lack of proper scientific knowledge and background in the DoE as the main factor that had obstructed negotiations over biosafety. The MoA asked how the DoE could undertake the professional tasks in this context. Suggesting the necessity of having a few CNAs rather than just one in the DoE, the Deputy of this Ministry claimed that CNAs should not engage in political activities, but that their decisions should be entirely scientific, in accordance with the evidence and facts.[106] The Deputy of the MoA referred to the organisation within that Ministry that is responsible for protecting plants as an example of an unbiased expert organisation: if it decides to quarantine a plant, even the Minister of Agriculture cannot change that decision. This statement clearly indicates that, in the view of the MoA, expert organisations can not only act independently of organisational or Ministerial interests, but also that their activities can be structured in a way that political bodies could and should not affect the decisions of experts.

The separation between promotional responsibilities and regulatory duties was another dimension of the view of the MoA, which believed that the overall biosafety policies

[104] Official voice recordings of the third session of the RC on 6 February 2007 (author's translation).
[105] Official voice recordings of the fourth session of the RC on 13 February 2007 (author's translation).
[106] Official voice recordings of the third session of the RC on 6 February 2007 (author's translation).

needed to be determined by politicians in the NBC, and not by scientists and experts. Discussing the proper role of the NBC, the representative of the MoA suggested that this committee should be constituted from politicians to determine the general policies and approaches of the country. The MoA claimed the necessity of having a clear distinction between expert bodies and policy-makers in a way that the former implements the law, while the latter play the role of goal-setters. Hence, in the view of the MoA, both science and politics need to be incorporated into the process, but in accordance with a clear separation between their roles, resembling a Weberian decisionist approach.

The approach of the MoH and the MoS remained unchanged from the CC on the necessity of giving the major role to biotechnology scientists, not only by empowering the expert organisations to become CNAs, but also by incorporating some experts into the NBC with a decisive role to make sure that policies are based on sound science. However, as I suggested in the last chapter, there was a difference between these Ministries with respect to the exact role of scientists in that the MoH suggested an approach closer to technocracy in comparison to the MoS. Table 6-1 summarises the assumptions of the Ministries and the DoE at the end of the RC.

6.5. Discussion of the results

In this section, I will sketch a revised table of the results of this phase of negotiations and will discuss the theoretical foundations of the new findings.

6.5.1. The new table of framing

Table 6-1 is an updated version of Table 5-1 characterising the framing assumptions and indicating the changes in the framing assumptions.

Table 6- 1 Divergent framing assumptions of Ministries and organisations at the end of Reviewing Committee

Elements of Framing	Contested Issues	MoH	MoS	MoA	DoE
Assumptions affecting understandings of the nature of the policy problem	*Presuming biotechnology safe or harmful?*	Framing Assumptions			
		Presuming biotechnology is safe unless there is proof of harm.	Presuming biotechnology is safe unless there is proof of harm.	Biotchnology is like other technologies (so might be harmful)	Presuming biotechnology is a harmful manipulation unless there is proof of safety
Assumptions regarding risk system	*Research activities as a source of possible risk?*	No. Researchers are the best people to ensure the safety of their work.	No. Research activities would not generate risks.	Yes. Researchers might fail to put in place safety measures and therefore impose risks.	Yes. Researchers might cause harm because of their interests.
	Lack of the law as a source of political risk?	-	-	Yes	-
	Scope of the risk and the causalities within the system?	Physical. Short-term, direct effects and target organisms.	[not enough information at this stage]	Physical and political [not enough information about the scope of each]	Physical, including long-term, indirect effects and non-target organisms.
Assumptions about ways of dealing with the problem (e.g. models of risk assessment and risk management)	*Role of biotechnological experts in the process of regulation?*	• Only biotechnological scientists should draft the biosafety law • Only biotechnological scientists should set the safety standards • Only biotechnological scientists should implement the law • Biotechnological scientists should play decisive role in general biosafety policy making	• Biotechnological scientists should contribute to drafting the biosafety law • Only biotechnological scientists should set the safety standards • Only biotechnological scientists should implement the law before releasing products • Biotechnological scientists and policy together should decide over releases • Biotechnological scientists should play a decisive role in general biosafety policy making	• Biotechnological scientists should be involved in drafting the biosafety law • Only biotechnological scientists should set the safety standards • Only biotechnological scientists should implement the law • Biotechnology scientists should not be involved in general biosafety policy	• Biotechnological scientists should only advise the deputies in drafting the biosafety law • Biotechnological scientists should only advise on setting the safety standards • Biotechnological scientists should not take part in implementation or enforcement • Biotechnological scientists should not be involved in general biosafety policy
	Separation of promotional from regulatory responsibilities?	No need for separation at all	No need for separation at all	• Separation between political goal-setting and other expert tasks • No separation in drafting	Separation in that there should be no decisive role for biotechnological scientists at different stages

The most obvious change between Tables 5.1 and 6.1 is the addition of an assumption about the scope of the possible risks and their causal effects as part of the conceptualisations of the risk system, as well as considering the political risk arising from a lack of a biosafety law as part of the risk-generating system. In this respect, for the DoE the problem was not only the direct, short-term effects of GMOs on target organisms, but also the possible long-term effects of these products as well as their influence on non-target organisms and their indirect impacts. In addition, the DoE was unhappy about developmental activities as a source of risk generation, due to its concerns about the risks of biotechnology and also because of its negative assumption that scientists' interests might lead them to overlook essential safety measures. As a result, the DoE suggested a process for biosafety regulation that excluded all bodies with promotional responsibilities from regulatory decision making.

The negative view of the DoE towards biotechnological experts was not shared by any other Ministry, although the MoA was worried about research activities because of technical concerns. The concerns of the DoE about the risks of biotechnology were not apparent in the views of the other Ministries. In sharp contrast, the MoH did not believe in such a broad scope of the risk assessment, fundamentally because this Ministry was not worried about biotechnological harm and, further, because those issues were assumed to be beyond the scope of current scientific deliberations, meaning that they were therefore not reliable scientific questions in the MoH's opinion. Conversely, the MoA was worried about the political risks stemming from the lack of a biosafety law, while the country was obliged to abide by its international commitments, having ratified the CPB. From this perspective, one part of the risk-generating system for the MoA was the lack of a biosafety law. The views of the MoS over the scope of the risk need more investigation, which I will turn to in the next chapter.

Table 6-1 also indicates some changes in the DoE's view *vis-à-vis* the role of promotional and sponsoring bodies in regulation. While at the outset, the DoE arranged the CC in a way that meant biotechnological experts could take part in the negotiation process, in particular as the senior representative of individual Ministries; the DoE however changed

its mind after the NBC session by inviting only Deputy Ministers as the people with the political responsibility to draft the biosafety law. Moreover, with respect to the responsibilities of the post-law CC (which was intended to draft operational rules and procedures), the DoE insisted that it should be composed of Deputy Ministers rather than biotechnological experts, presuming that scientists might act partially in the interests of their research activities.

6.5.2. Identified assumptions and the literature

It is possible to summarise the new findings under two broad headings: firstly, the suspicious view, as held by the DoE, of organisations and individuals (especially biotech researchers) with promotional responsibilities, which was observed by Wynne (1980 and 1982); and secondly, the disagreements over the scope of the possible risks that should be considered in regulatory processes (Millstone et al 2004 and 2008).

Wynne observes that trust in institutions lies at the heart of risk perceptions (1980). He further argues that in the Windscale case, the critics of the scientific experts did not approach the issue technically (unlike the experts, who framed the issue technically), but instead framed the issue presuming that the promotional bodies would be untrustworthy and biased because they might not consider proper safety measures at the expense of developmental interests (Wynne 1982). These findings seem parallel to the views of the DoE in the present case, as this department was extremely concerned about the partiality of promotional bodies in regulation.

Millstone et al (2004) pointed to different views with respect to the scope of risk assessments as a matter of differences between countries as to whether or not various risks should be considered, including for example direct/indirect risks, short/long-term risks and risks to target/non-target organisms. Some of the disparities in the Iranian system could be attributed to the differences in the views of the involved organisations about the scope of the risk that should be considered by the biosafety law and in the process of risk assessment.

6.6. An account of the policy output

In the remaining part of this chapter, I turn to the analysis of the policy outputs of this stage, which was a draft biosafety law. My inquiry in this chapter has shown that the framing assumptions did not change substantially during this stage of negotiations when compared to the elicited assumptions from the CC sessions, discussed in the previous chapter. Therefore, the question is: if the framing assumptions remained contradictory and unchanged, how did the RC end with a draft biosafety law as an output, which was then sent to the NBC and the Cabinet for final approval?

It might be worth pointing to a media interview with the head of the office after the end of the RC, in which he stated: "we proceeded at a good pace with agreement over different parts of the draft. However, there was only a disagreement between the MoS and the MoA on the scope of the law, which could be resolved in the NBC or by the Cabinet through the interaction of the related Ministers." (Interview with MehrNews Agency, 29 July 2007)[107]

Therefore, the question is how a draft was produced in the end, when the members had not generally been in agreement. To put it differently, if the members had the power to insist on their different and to some extent contradictory framing assumptions, how did they end up with a draft biosafety law? Why had the failure of the CC to produce a draft not reoccurred in the RC?

Scrutinising the final session of the RC, held on 8 of May 2007, is very revealing in this respect. During this session the head of the DoE requested the signatures of approval of the MoS and the MoA on the draft, as she already had the signature of the MoH.[108]

At the start of this session, the MoS expressed its concerns over including 'production' activities in the scope of the law, which mainly referred to the production of GM products in factories. This Ministry asked that production be exempted from the scope of the final draft. Meanwhile, the MoA pointed out that if they were to change something

[107] http://www.mehrnews.com/fa/NewsDetail.aspx?NewsID=525412
[108] The MoH signed the draft as it exempted pharmaceuticals and therefore the biosafety law had less to do with this Ministry.

with respect to the scope of the law, not only production but research should be covered by the law. Further, in calling the current draft an unprofessional text, the MoA claimed that the necessary changes were about much more than just the scope of the law, because the location of the office of the secretariat should also be changed from the DoE to the MoA. Intriguingly, the head of the DoE replied that this final session was not going to discuss the topics that had previously been discussed, otherwise the DoE would propose changing the scope to include pharmaceuticals too (given the fact that the MoH had devoted immense effort to their exclusion).[109] This short dialogue indicates that even at the last session of the RC, disagreements remained unresolved.[110]

Finally, the head of the DoE pointed to the minutes of the previous sessions containing the signatures of both the MoS and the MoA. She therefore asked the members to end the debates at that point and sign the final draft, warning that otherwise even the notes of the previous sessions were sufficient and that there was no need for this final approval signature. In other words, she emphasised that the office was able to pass the draft to the NBC, regardless of having the final approval of all the Ministries. After more discussions, lasting over an hour, eventually the MoS and the MoA did not sign the specific article determining the scope of the law, although they had signed other parts of the draft in the previous RC sessions.

At the end of the session the head of the DoE stated that although the MoA and the MoS disagreed about the scope of the law, this draft would be passed to the government as the final version. In the view of the DoE, if the Ministers of Agriculture and Science were concerned about this issue, they could talk together and find a solution. The head of the DoE then announced that "this was the last session, and the work on the draft is finished."[111] On this basis, we can better understand the meaning of the words used by the head of office in his interview cited above, in which he stated that the MoA and the MoS only disagreed over the scope of the law. In fact the draft policy was the version enforced and to some extent selected by the DoE, which had not only chaired the session, but which also had control over the minutes.

[109] MoH was absent at the last session as it had previously signed the draft.
[110] Official voice recordings of the eigth session of the Reviewing Committee on 8 May 2007 (author's translation).
[111] Ibid

There were plenty of other occasions during the RC sessions when the head of the DoE exerted power to influence the draft. However, instead of detailing those examples, it would be more revealing to concentrate on the text of the RC's final draft to examine to what extent it was close to the framing assumptions of the DoE.

6.6.1. Analysing the draft

The claim of this chapter *vis-à-vis* policy output is that although the framing assumptions that underpinned the controversies remained largely unchanged, the policy outcome could be best explained by noting the power relations in the policy process rather than by reference to the framing assumptions. I have argued that the head of the DoE exercised power to influence the decisions and produce a draft at the end of this stage by deciding which perspectives should prevail.

However, the power relations could not suffice to explain the content of the policy output. The content of the policy output can be understood in relation to the framing assumptions of the dominant power, i.e. the DoE. In the other words, my main claim is that we can best understand the policy output by combining the power relations with the framing assumptions, or rather that power determined which framing assumptions prevailed. In the last part of this chapter, I will discuss the text of the draft biosafety law as the output of the RC and will compare it with the framing assumptions of the DoE to examine the validity of this claim.

Essential parts of the final draft could be summarised as follows:[112]

- Emphasising a 'precautionary approach' for confronting or mitigating the possible risks of biotechnology. In addition, only the CPB was referred to in this part as the most important international agreement without referring to national development plans emphasising the promotion of biotechnology.
- In the definitions, 'release' was defined as any type of non-contained use of GMOs, while all types of research, even field trials, were defined as experiments that should be done in circumstances of contained use without any possibility of

[112] I received a copy of the final draft from the office of the secretariat in the DoE.

interaction with the environment. This reflects the extreme concerns of the DoE over the risks of GM products or processes that there should not be any possibility of interaction with the environment in the process of research, before ensuring there would be no risk. This also reflects the lack of proper biotechnology knowledge inside the DoE.

- The structure of the NBC proposed in the final draft was to be established solely with the Ministers and the First Deputy President. However, in the absence of the Deputy, the head of the DoE would chair the sessions. The DoE dismissed the arguments of the MoH and the MoS for having three biotechnological experts in the NBC as the providers of sound scientific knowledge and decision making. In addition, the following Ministries were involved: Foreign Affairs, Trade, Industry and Defence, which had previously endorsed the approach of the DoE in the CC sessions.
- The post-law CC proposed in the draft was to be constituted by the Deputy Ministers, not senior representatives of Ministries who could be biotechnological experts. This committee would be chaired by the head of the DoE. This proposal discounted complaints of other ministries that the post-law CC should be composed of experts rather than politicians.
- The office of the secretariat was to be located in the DoE which would also hold responsibility as the National Focal Point (NFP) for international communications. The office was also supposed to monitor and assess the implementation of the decisions of the NBC. This also reflects the intention of the DoE in taking control over the office of the secretariat amidst ever-increasing disagreements from other Ministries.
- Ministerial and organisational groups were not to be CNAs, but were proposed to be established under their organisational and Ministerial mandates as providers of information and knowledge. As they were not authorised to be CNAs by the draft, they had therefore not been given power to make decisions or issue authorisation for the release of GMOs. This was also in opposition to the concerns of the MoA, the MoS and the MoH, who wanted to become CNAs

with the right of decision making, but in favour of the concerns of the DoE over authorising the promotional bodies that might be affected by their own interests.

- Authorisations, according to the draft, should be done in interaction with the office of the secretariat of the NBC, which was also to be in the DoE. That office would ask other organisational groups to be involved in the process of decision making (including the DoE) by providing information and knowledge. If all involved organisations were agreed, authorisation would be allowed. Note that this included the DoE and the office could always ask the environmental group of that department to be involved in the process, and, according to the framing assumptions of the DoE about biotechnology, they should make sure any certain products were safe before agreeing with their release or marketing. This means that the DoE could be involved in all cases of authorisation and play a decisive role.
- The scope of the draft law covered all activities in relation to management, release, use, exploitation, export, import, handling, movement and shipment of agricultural GMOs (although pharmaceuticals were exempted) and their derivatives. Thus, production was considered in the scope of the law by the draft (i.e. the DoE had set the scope in this way), while the MoS and MoA were allowed to negotiate further about this subject in the Cabinet.
- The draft stressed that the rules governing research would be determined in the NBC, which was designed by the DoE, eliminating biotechnological experts but including the Ministries of Foreign Affairs, Trade, Industry and Defence. This means that even research activities were not clearly exempted by the draft as the First Deputy President had previously suggested.

The above discussion conveys the spirit of the framing assumptions of the DoE: extreme concerns over the safety of biotechnology as well as about the bodies involved in biotechnology promotion, calling for strict monitoring and control over their activities by an impartial organisation, along with rejecting any role for promotional bodies in implementing the law.

In short, although framing assumptions alone could not explain the policy output, knowing the power relations and the dominant organisation, those framing assumptions could contribute to understanding, or even predicting the policy output.

6.6.2. The process in the Cabinet

The final session of the RC was held on 8 May 2007. In an interview on 29 July 2007, i.e. less than three months later, the head of the office reported that the second session of the NBC[113] had been held and the controversies between the MoA and the MoS over the scope of the law remained unresolved even after that session.[114] This type of reporting indicates at the very least that the controversies were continuing at the high level of decision making at that time, at least between the MoA and the MoS.[115]

Although there is a shortage of information about the policy process at the high level of decision making and between Ministers, there are some indications that at least the MoA and the MoS were in conflict with each other over the scope of the law. As an example confirming that the controversies were still alive, the Minister of Science, in an interview on 25 September 2007, i.e. nearly five months after finishing the RC discussions, said that he had asked the DoE to trust the approach of the MoS to biosafety.[116] He stressed that the MoS could provide sound scientific reasons that biotechnology would not harm the environment. The draft biosafety law was finally approved by the Cabinet on 28 May 2008, a year after the final session of the RC and nine months after the second NBC session.[117]

The final draft, which was approved by the Cabinet and sent to the Parliament, contained no sign of change from the final draft of the Reviewing Committee.[118] The only alteration to the content was about the scope of the law, from which 'production' was excluded (i.e. the MoS prevailed over the MoA on this issue). Nonetheless, the government had split

[113] Unfortunately I have not had access to the data of this session. Moreover, there was not a tape in the office of the secretariat (as I have seen their archives and there was no tape of the second NBC).
[114] http://mehrnews.com/fa/NewsDetail.aspx?&NewsID=525412
[115] Mainly because the MoH could exempt the pharmaceuticals and the DoE could dominate its view over the law. Therefore, just the MoA and MoS were clearly disagreeing about the scope of the law.
[116] http://mehrnews.com/fa/NewsDetail.aspx?&NewsID=558219
[117] The official letter of sending the draft bill to the Parliament is available on the Parliament's website at http://tarh.majlis.ir/files/20757122ID-176.pdf. In the letter of transmission, the President stated that the bill was approved by the Cabinet on 28 May 2008.
[118] The official bill of the Government that was sent to the Parliament in available on the Parliament's website at http://tarh.majlis.ir/?Report&RegId=176

the draft into two separate parts: the first part determining the operational structure, and the second part covering other issues. The Cabinet decided to send just the second part to the Parliament and approved the first part as a governmental stipulation determining the structure of the NBC, the CC, the office of the secretariat and the Ministerial and organisational groups. On 5 August 2008, Parliament announced that it had received the government's Biosafety Bill.[119] In the next chapter, I will discuss the Parliamentary process and the changes made to the bill in the Agricultural Committee of the Parliament.

[119] Ibid

Chapter 7. The Third Phase of Negotiations: Parliamentary Process, August 2009 - May 2009

7.1. Introduction

The last chapter investigated the process by which a draft biosafety law was prepared by the RC and passed to the Parliament. The output of the RC was a draft intimately reflecting the views and assumptions of the DoE over biosafety. In this chapter, I shall discuss the process in which the Parliament amended the Government's bill, and finally passed a new version as Iran's formal biosafety law.

In this chapter, I will not follow the style of discussion of two previous chapters because there has been no access to voice recordings or other similar minutes regarding the sessions of the Agricultural Committee of the Parliament, the main body that dealt with the proposal before transferring the bill to the main Chamber. The sessions of this Committee were held by inviting the deputies and senior representatives of the MoA, MoS and MoH as well as the head of the DoE and the head of the office located in the DoE, in addition to several other biotechnological experts. These sessions finally resulted in an amended draft of the biosafety law.

I conducted a first round of interviews after the end of the RC in summer 2008, but before the start of the Parliamentary sessions, and a second round of interviews were conducted in summer 2009 after passage of the law by the main Chamber. I will use those data to organise this chapter. After a short description of the third phase of legislation in the next section, I shall discuss findings from the interviews based along several dimensions. Firstly, I will track the changes of framing assumptions to find out to what extent the framing assumptions of the protagonists changed after the previous Governmental negotiations and during the Parliamentary discussions. Secondly, I will try to populate the empty or less fully-explained cells of the table of framing assumptions, using the data from the second round of interviews as the final viewpoints of the protagonists that might be different from their assumptions in the earlier stages.[120]

[120] Nonetheless, as I accessed the minutes of speeches in the Chamber discussing the biosafety law, including the speeches of the head of the DoE, I will use those data at the end of this chapter as a complementary source of information along with some other available documents and letters.

Based on those assumptions, I will discuss the policy output of the Agricultural Committee of the Parliament by further testing the hypothesis of the previous chapter *vis-à-vis* the power relations during the sessions. In addition, I shall describe the process in the main Chamber which led to enacting the biosafety law by drawing on the minutes of the speeches in the Chamber over the three days spent discussing the biosafety bill, i.e. 12, 13 and 17 of May 2009.[121]

7.2. Process of Legislation

On 6 August 2008, the Parliament of Iran announced receiving the Government's bill for the biosafety law. After finishing formal administrative procedures, the bill was sent to the Agricultural Committee of the Parliament on 26 August 2008, as the most relevant committee for further discussion, before transferring it to the Chamber. Nearly two months were sufficient for this committee to publish an initial amended draft on 15 October 2008, including substantial changes compared to the Government's bill.[122] Less than three months later on 1st January 2009, the Government asked Parliament to withdraw its suggested bill which was the result of RC negotiations.[123]

In a radio interview after the withdrawal of the Government's bill, the head of the Agricultural Committee of the Parliament claimed that in the sessions of the Agricultural Committee that resulted in the amended draft, all Ministries and organisations who had been formerly involved in the CC and RC negotiations were present, and all agreed the alterations and modifications.[124] He suggested that if it were possible to continue the sessions, it would probably end all controversies by developing a final draft.

However, he did not mention or explain why the DoE as the office of the secretariat had urged the Government to withdraw the bill. The head of the DoE implied that the main reason for withdrawing the bill was the devastating alterations introduced in the

[121] It is worth noting that the Chamber session is not an entire policy process, but a final stage of decision making through short speeches and a voting system.
[122] It is also available in the Parliament's website at www.tarh.majlis.ir
[123] The Persian calendar is different from the Western on, and January is not holiday in Iran.
[124] Radio 'Javan' (meaning youth) , on the scientific programme named 'Enekas' (meaning reflection). The voice file of this interview is available on the www.iranseda.com website which contains the archives of the Iranian Radio Programme. However, I do not have the exact date of the transmission, though it is clear that it was after the withdrawal of the Government's bill and before the suggestion of a new bill by the Agricultural Committee of the Parliament.

Agricultural Committee sessions, which had changed it into a biotechnology development law rather than biosafety one.[125]

In the same radio interview, the chair of the Agricultural Committee of the Parliament also unveiled the plan of this committee to continue the sessions and submit the final proposal to the Parliament as a new biosafety bill. His prediction came true; on 26 January 2009 Parliament announced receiving the new bill for the biosafety law from the Agricultural Committee. Indeed, when the DoE urged the Government to withdraw the bill, it likely did not expect that the Agricultural Committee of the Parliament would submit its version as a new bill less than a month after that withdrawal. The main Chamber then spent three days discussing the biosafety proposal on 12, 13 and 17 May 2009, and the biosafety law of Iran passed on 17 May 2009.

7.3. Interviews and Framing Assumptions

As I have indicated previously, there was a problem in accessing information about what happened in the Agricultural Committee sessions that was as detailed as the information I obtained for the process of negotiations in the Government. In the following paragraphs, I will discuss the insights that came from my interviews to enrich our understanding of the framing assumptions, when compared to the findings of the previous chapters. Intriguingly, the interviewees highlighted the same points that they had emphasised in the CC and the RC, showing the overall stability of their framing assumptions. Nonetheless, I shall use relevant documents as other sources of data. With a detailed picture of the framing assumptions it should be possible to analyse the policy output of this stage.

7.3.1. Policy Problems: Safety or harm of biotechnology influencing the definition of the problem

Regarding the assumptions about the harm and safety of biotechnology that largely affect the definition of the problem in hand, protagonists revealed more, especially about their general views of 'technology' and 'technology development'.

[125] http://www.jamejamonline.ir/papertext.aspx?newsnum=100915557139

7.3.1.1. The MoH

The representative of the MoH on 5 July 2008 hailed biotechnology as a masterpiece for helping humans, aiding the development of human life and addressing some unsatisfied needs such as world hunger. He described biotechnology as a major tool for solving current problems in health, food and agriculture and subsequently provided several examples of how biotechnology could help humans through manipulating the genetic structure of foods or medicines as further means of support for his argument.

Regarding possible risks from this technology, he argued that there is no difference between biotechnology and other technologies. He suggested that a problem might arise from abusing biotechnology, similar to other technologies, in the same way that a knife can be used to kill people, but this is not a legitimate reason for banning the production or sale of knives. In representing biotechnology as primarily beneficial, like tractors which are beneficial for farmers, the representative of MoH argued that safety concerns should be focused on preventing abuses of biotechnology.[126]

The Deputy Minister of Health also endorsed this view by suggesting that there is no difference between modern and traditional biotechnology. In the latter, crops were modified externally through the mechanism of natural selection, while in the former, genes are being modified internally by humans. The view of the MoH was that there is no basis for fearing risk or harm from biotechnology. The Deputy Minister emphasised that a GM product is no different from a natural product. In the view of this Ministry, there is no difference between the risks of biotechnology and those of other technologies, and fundamentally there is no safety difference between genetically modified and natural foods or crops. The MoH had always been very relaxed in terms of any scientific development and argued that research activities should be left free of regulation.[127]

7.3.1.2. The MoS

On 2 July 2008 the representative of the MoS claimed that genetic engineering is a process for reducing the required time for gene transfer. There is no doubt that genes are

[126] Interviews on 5 July 2008 and on 13 August 2009.
[127] Interview on 29 June 2008.

transferring in the environment in traditional plant breeding, and by gene manipulation scientists are just speeding up processes that otherwise might have taken thousands of years. All technologies might pose some risks and biotechnology is not distinctive in this way, just like cars or aeroplanes, for which possible risks are assessed, managed and accepted. As humans need transportation and have accepted those technologies by reducing their possible negative effects, biotechnologists try to examine a variety of products over seven or eight years to find a workable product, and one that confers minimum risk.[128]

These assumptions mean that, in the view of the MoS, there is no difference between biotechnology and other technologies, considering it as a safe innovation in principle. In addition, on 24 September 2007, after finishing the RC sessions and before sending the draft to the Parliament, the Minister of Science argued that the DoE was extremely suspicious about biotechnology, whereas the MoS had sound scientific reasons for its claim that biotechnology is safe and no different from other technologies.[129]

7.3.1.3. The MoA

In an interview on 27 July 2008, the representative of the MoA argued that over the time, trust in GM products and their safety has increased and will continue to do so. However, looking at the profile of commercialised GM products, more than 90 percent of them at the time were soya, canola (oil seed rape), cotton and corn, which mostly are not for direct human consumption. He argued that therefore the concerns for human health might be higher than the concerns for the environment. He added that the possibility of causing harm to the environment would be near to zero, as the process of gene transfer has always occurred in nature. In his view, because it is not possible to say that the risks are exactly zero there is therefore a need to consider some security measures for biotechnology.[130]

The head of the Agricultural Biotechnology Research Institute of Iran (ABRII) compared biotechnology with aeroplanes to argue that, like the latter which need special safety

[128] Interviews on 2 July 2008 and on 14 August 2009.
[129] http://mehrnews.com/fa/NewsDetail.aspx?&NewsID=555981
[130] Interviews on 27 July 2008 and on 11 August 2009.

measures, the former also requires specific treatment to be used and applied.[131] In this sense, the view of the MoA *vis-à-vis* biotechnology was that it was like other technologies in that it might impose some risks along with its benefits.

7.3.1.4. The DoE

In an interview on 22 July 2008, the representative of the DoE tried to highlight the basis of that department's concern by interpreting the emergence of the CPB as a result of widespread similar concerns all around the world. He claimed that the warnings over increasing development of biotechnology led the Convention on Biological Diversity (CBD) to initiate the CPB, aiming at devising managerial and controlling mechanisms in relation to the risks of biotechnology. The root of those concerns, in his view, could be traced to the history of science that on one hand conferred substantial benefits and on the other hand generated risks and harm. Referring to the case of air pollution from cars, the DoE argued that it is necessary to exercise caution, as many negative effects of previous technologies were only recognised several years after their introduction. In this respect, there might be problems associated with the process of technological development, and this calls for the necessity that researchers should demonstrate that their products are safe.[132]

These statements clearly show the overall concern of the DoE, not just about biotechnology, but over negative effects of many kinds of technological developments. The head of the office of the secretariat in the DoE, in a separate interview on 29 June 2008, claimed that biotechnology is potentially worse, as the harm of this technology is generally irreversible.[133] Therefore, it is different from other technologies, and calls for an entirely different safety approach.

[131] Interviews on 9 August 2008 and on 9 August 2009.
[132] Interview on 22 July 2008.
[133] This emphasis on irreversible harm was based on their view that if biotechnology imposes harm, the harm to the environment will certainly be irreversible. However, there was no disagreement on this assumption between the members as they were all agreed that if such types of harm the DoE envisaged do happen, that harm will be irreversible. The contention instead was about whether or not those kinds of harm could or might arise.

7.3.2. Risk system

Interviews confirmed the previous positions of the protagonists regarding whether or not to consider research as a source of potential risk, and also on the issue of whether a lack of a biosafety law was a source of political risk, as in the view of the MoA. Hence, the interviews did not add new information in those respects. Regarding the scope of the risks and the bounds of causalities within the system, I obtained the views of the MoA and the MoS from interviews as follows.

7.3.2.1. Scope of Risks

With respect to the scope of risks, the MoS suggested that assessing the long-term, indirect impacts as well as the effects on non-target organisms by science might not always be possible. For this purpose, there are scientific means of extrapolation, for instance from short-term assessments, that could help to predict the long-term effects, but in principle there is no way to empirically address these types of concerns definitively. Therefore, the only way of dealing with this would be to accept scientific judgments, but not to wait a long time for these uncertainties to be diminished.

The view of the MoA about the scope of risks and short/long-term and direct/indirect effects and effects on target/non-target organisms was concentrated on the idea that risks would vary case by case and therefore it was not possible to identify the scope of the risk as a general rule prior to having particular cases at hand. Nonetheless, an interpretation of this view is that for the MoA, there might be some instances in which there would be a need to consider long-term, indirect effects and those on non-target organisms, but perhaps not in all instances.

7.3.3. The role of biotechnological experts in policy prescriptions

In terms of the ways of addressing the problem and the proper role of different agents, especially biotechnological experts, the interviews revealed new information by reflecting on the experience of recent years and the process of negotiations when the DoE controlled the office.

The MoH provided more details in the interview about its technocratic view mainly by criticising the lack of expert knowledge in the DoE. The representative of the MoH defined biosafety as knowledge of how to control biotechnology, meaning that it was defined within the scope of biotechnology science to devise the proper control measures. Therefore, in his view, non-biotechnologists and non-experts should not be allowed to be involved in the subject. He argued that all the current difficulties with the biosafety law came from involving non-experts in the legislative process, especially the DoE which suffered from a lack of scientific knowledge. To him, that department could not tell wrong from right and therefore imposed too many problems on biosafety.

The senior representative of the MoH argued that having non-scientific views had undermined the decisions on biosafety. In his words, it could not be valid to oppose biotechnology by drawing on imaginings or by highlighting non-scientific possibilities. Moving beyond scientific principles and considering non-scientific possibilities would lead to the illusion that, for instance, all humans are carrying a bomb in their stomachs because there are several microbes in the atmosphere, while everybody knows that this is not the case. Therefore, it would not be legitimate to deal with this issue according to political considerations or ideas, but only according to science.[134] In a scientific system, decisions should be purely scientific. Therefore, the MoH stressed that biosafety could not be separated from biotechnology, as it concerns the measures that scientists need to address in their developmental activities, and those scientists are the best people to identify those measures.[135]

For the MoS, biosafety was also framed within the borders of biotechnology science without including any contribution from politics. The representative of the MoS believed that the difficulties in the Iranian system of biosafety had arisen because the issue had been treated in a political way. He added that taking a political approach to biosafety entailed undermining the scientific approach. Referring to some instances during the negotiations, he noted that the head of the DoE several times asked the others to consider something without providing any scientific reasons, and that was not the right approach because biosafety needed a scientific and not a political approach. In his view, biosafety

[134] These ideas remind us the technocratic analysis of Miller (1997) as I discussed in chapter 3.
[135] Interviews on 5 July 2008 and on 13 August 2009.

was not like a political law, but was a professional field that needed a sophisticated, expert approach. Unfortunately, the head of the DoE was not an expert in that field, and as there were some biotechnological researchers who could not recognise the true nature of the field, how could it be possible for the head of the DoE to understand the issues? The fundamental approach to biosafety, in the view of MoS, should be scientific, with no interventions from the political side.[136]

The MoA emphasised a clear distinction between science and politics, presuming science to act independently of values and vested interests. The representative of the MoA argued that there must be a clear separation between science and policy in that science would implement the law by undertaking risk assessments, deciding over authorisation and risk management, while people with political responsibilities as the members of NBC should contribute to setting general policies about biosafety according to the situation of the country, such as policies over imports and exports of GMOs.[137] These ideas of the MoA were quite close to the provisions of the decisionist model. The MoA representative suggested that the prevailing difficulties had come from the lack of expertise within the DoE, which was supposed to uphold a scientific view but couldn't. That department had neither enough knowledge and academic training nor the organisational infrastructure to deal with biosafety, according to the senior representative of the MoA.

For the DoE, biosafety should be decided at a political level, and the representative of this department revealed a more negative view towards domestic biotechnological researchers and other organisations with promotional responsibilities. He stressed twice that it was not easy to understand the behaviour of Iranian biotechnological experts with regard to biosafety, because on the one hand there had been several reports indicating problems with biotechnology, and on the other hand the Iranian biotechnological experts insisted that there could be no risks from biotechnology. He argued that this paradox would lead to a conclusion that the Iranian biotechnological experts might prioritise their professional interests over considering the safety of the environment, particularly the protection of biodiversity.[138]

[136] Interviews on 2 July 2008 and on 14 August 2009.
[137] Interview on 27 July 2008.
[138] Interview on 22 July 2008.

The head of the DoE stressed repeatedly the problems that might arise from incorporating biotechnological experts in regulating biotechnology in the sessions of the main Chamber.[139] In addition, the head of the office of the secretariat claimed several times that those biotechnological experts that were representing the Ministries with promotional responsibilities would try to maximise their benefits rather than considering the safety of the environment or human health.[140] This analysis complements the understanding of the approach of the DoE in excluding biotechnological experts as much as possible from biosafety regulation because of their participation in promoting biotechnology, and gaining benefits from developing this technology.[141] Therefore, DoE suggested just a consulting role for biotechnological experts or other expert organizations, excluding them from any decisive roles in biosafety regulation.

7.3.4. Summarising the findings

Table 7-1 represents a more complete picture of the diverse framing assumptions of the Ministries and the DoE of the Iranian biosafety legislation system during and after the Parliamentary discussions based on two sets of interviews: before and after that last stage of negotiations. Regarding the dynamic of the overall process, the findings show the overall stability of the framing assumptions from the start of the CC to the passage of the law.

[139] Minutes of the Chamber negotiations on the biosafety law on 12, 13 and 17 May 2009.
[140] I met him several times when I was going to the DoE to listen to the voice recordings of the sessions, and each time I would chat with him for 10-15 minutes. He repeated this view two or three times.
[141] Therefore she was not worried about science in general, but about the benefits for biotechnologists of developing biotechnology.

Table 7- 1 Divergent framing assumptions of Ministries and organisations in the Parliamentary process

Elements of Framing	Contested Issues	MoH	MoS	MoA	DoE
Assumptions affecting understandings of the nature of the policy problem	*Presuming biotechnology safe or harmful?*	Framing Assumptions • Like other technologies, beneficial, with the potential of abuse • Biotechnology is like other technologies • So biotechnology is also beneficial and safe if there is no proof of harm	• Like other technologies are beneficial, if their risks are controlled • Biotechnology is like other technologies • So biotechnology is also beneficial and safe if there is no proof of harm	• Other technologies are beneficial, but might generate risks • Biotechnology is like other technologies • So biotechnology is also beneficial and should not be considered essentially harmful if it develops according to official safety measures	• Other technologies generated problems while conferring some benefits • Biotechnology is worse, as its problems exceed its benefits • There is a need for proof of safety
Assumptions regarding the risk system	*Research activities as a source of possible risk?*	No. Researchers are the best people to ensure the safety of their work.	No. Research activities would not generate risk.	Yes. Researchers might fail to adhere to safety measures and therefore pose substantial risks.	Yes. Researchers might follow their interests and therefore cause harm.
	Lack of the law as a source of political risk?	-	-	Yes	-
	Scope of the risk and the causalities within the system?	Physical. Short-term, direct effects on target organisms.	Physical. Assessing long-term, indirect and non-target organisms according to scientific judgments	Physical as well as political Scope of the physical assessment should be identified case by case	Physical. Long-term, indirect effects and effects on non-target organisms should be assessed.
Assumptions about the ways of dealing with	*Role of biotechnological experts*	• Only biotechnological	• Biotechnological scientists	• Biotechnological scientists	Essentially political and managerial

problems (e.g. models of risk assessment and risk management)	*in the process of regulation?*	scientists should draft the biosafety law • Only biotechnological scientists should set the safety standards • Only biotechnological scientists should implement the law • Biotechnological scientists should play a decisive role in general biosafety policy	contribute to drafting the biosafety law • Only biotechnological scientists should set the safety standards • Only biotechnological scientists should implement the law before releasing products • Biotechnological scientists and policy should decide together over releases • Biotechnological scientists should be involved in the general biosafety policy	contribute to drafting the biosafety law • Only biotechnological scientists should set the safety standards • Only biotechnological scientists should implement the law • Biotechnology science should not be involved in the general biosafety policy	• Biotechnological scientists should only advise their organisations in drafting the biosafety law • Biotechnological scientists should just advise in setting safety standards and risk assessments • Biotechnological scientists should not take part in decisions about implementation and enforcement • Biotechnological scientists should not be involved in general biosafety policy
	Separation of promotion from regulation?	No need for separation at all	No need for separation at all	• Separation between political goal-setting and other expert jobs • No separation in drafting	• Separation in that there should be no decisive role for biotechnological scientists at different stages

The interviews revealed two new important findings about the framing assumptions of the organisations. First were the general views towards technology that help explain considerable differences in the approaches to regulating biotechnology. Moving from the MoH to the DoE along the horizontal axis of Table 7-1, it seems that emphasis on the downsides of the technology increases. For the MoH, problems of the technology might come from abusing it; for the MoS there could be possible risks; for the MoA technology might generate risks; and finally for the DoE technology has been envisaged as a source of many problems that need specific attention. The second finding is regarding the debate about conceiving biotechnology as being like other technologies or as something essentially different. In this respect, it was only the DoE that perceived biotechnology as an entirely different and more dangerous technology compared to other technologies.

7.4. Policy Output

The result of the sessions of the Agricultural Committee of the Parliament was an entirely different draft compared to the Government's bill, although there was no change to the framing assumptions of the protagonists. For a better understanding of this policy output, and according to the hypotheses of the previous chapters, I will investigate the power relations in the sessions of the Agricultural Committee of the Parliament to find out whether there was a dominant power (certainly not the DoE) to impose its framing assumptions, or whether the draft was changed and produced in a different way.

As part of the Parliamentary process, and because the Agricultural Committee of the Parliament was the main body to deal with the bill, those MPs who were members of this committee had the power to change the draft. However, as they were not experts in biotechnology or biosafety, MPs on the Agricultural Committee invited deputies and senior representatives of the Ministries involved in the former negotiations (i.e. the MoH, the MoS and the MoA) as well as the DoE and some other biotechnological experts, including the researcher who developed the Iranian GM rice.

From the outset, there were indications that the MPs on the Agricultural Committee trusted the opinions of biotechnological experts, some of whom were the representatives

of the MoH, the MoS and the MoA. Their trust in the biotechnological experts became clear when, just a day after withdrawing the Government's bill, representatives of the MoH, the MoA and the MoS along with some biotechnological experts gathered in the Pasteur Institute (PI) located in the MoH to discuss the decision of the Government and the future of biosafety. The head of the Agricultural Committee also joined them, and perhaps it was in that session that he was persuaded to submit the amended draft as a new biosafety bill in response to the Government's withdrawal.[142]

In that session, he stated that the Government's decision to withdraw the bill had wasted over 100 hours of sophisticated work in the Agricultural Committee of the Parliament. He added something that showed his general view towards biotechnology was close to those of the MoH and the MoS: "some people argue that biotechnology is essentially dangerous, like a cake containing a bomb. This is not true; biotechnology is like other technologies that might confer some risks. In this sense, electronics also could generate some risks, but this is not a reason to ban that technology."[143] In a radio programme after the above meeting, and before submitting the new bill, the head of the Agricultural Committee of the Parliament indicated that this committee had modified the Government's bill after getting advice from various biotechnological experts to clarify and improve it.[144]

In the second round of interviews, representatives of the MoH and the MoS confirmed that they had participated in those sessions and put forward their views, while MPs were the final decision-makers who mainly adopted their judgments as sound and scientific.[145]

Moreover, there are some official letters confirming that the MoS and the MoH supported the Parliament's bill and its approach. On 23 February 2009, the MoH sent a letter to Parliament indicating that the current draft bill was satisfactory.[146] On 13 April 2009, the representative of the MoS, by emphasizing what he thought to be the positive

[142] http://mehrnews.com/fa/NewsDetail.aspx?NewsID=810913
[143] Ibid
[144] Radio 'Javan' (meaning youth) , the scientific program named 'Enekas' (meaning reflection)
[145] Interviews with the senior representatives of the MoH on 14 August and of the MoS on 13 August 2009.
[146] I have a copy of this letter, though the MoH did not let me know the number of this letter.

aspects of the Parliament's bill, claimed that enacting the amended draft would be a tremendous help for the country as a whole.[147]

7.4.1. Analysing the amended draft

Hence, knowing that many of the opinions of the representatives of the MoH and MoS influenced MPs, as well as knowing the framing assumptions of those Ministries, it may not be difficult to predict that the amended draft would be radically different from the Government's earlier bill.[148]

While the Government's initial bill, which was a reflection of the views of the DoE, was trying to control biotechnology through exerting political control over biotechnology developments, the amended draft became a version that considered biotechnology to be just like other technologies and therefore mostly beneficial, delegating authority to the Ministries involved in developmental activities as the relevant expert bodies, and letting research and development activities be conducted without tough regulations. The amended draft, which was turned into a new bill proposed by the Agricultural Committee of the Parliament after the withdrawal of the Government's earlier bill, conformed to those characteristics.

In comparison to the Government's bill, which had devoted a great deal of effort to identifying infractions and penalties, the Parliament's bill left the decision making *vis-à-vis* violations to a three-member committee constituted of three biotechnological experts from the MoH, the MoS and the MoA, and if they could not resolve the problem, then to the judiciary. The new bill mainly tried to clarify the responsibilities of the organisations involved and the implementation structure, with an emphasis that those implementing authorities that opposed requests without any scientific proof of harm would be acting unlawfully and should be prosecuted.

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[147] http://mehrnews.com/fa/NewsDetail.aspx?&NewsID=859409
[148] However, the MoA was not trusted by the MPs as much the MoH and MoS.

The changes in more detail were as follows:

- Eliminating the precautionary approach from the opening clauses
- Allowing research activities to be conducted free of regulation before the stage of release (even field trials would be free of restrictions)
- The NBC should be established and composed of the Ministers of the MoH, the MoS, the MoA and the DoE as well as two biotechnological experts, and chaired by a Deputy President (i.e. not the head of DoE and not necessarily the First Deputy)[149]
- The office of the secretariat should be shifted to the office of President rather than the DoE
- The MoA as the National Focal Point (NFP) for international communications
- Failure to issue authorisations without scientific proof of harm was deemed to be a type of infraction that could lead to prosecution
- There was to be no post-law CC. The responsibility for authorisation was delegated to the MoH, the MoA and the DoE, each within a specific domain. The remit of the DoE was confined to natural parks or wild areas, while farms and urban areas were considered under the authority of the MoA
- The draft did not cover pharmaceuticals.

This output from the Parliamentary negotiations confirms the suggestion and prediction that the dominant framing assumption would shape the policy output, and therefore knowing the power relations as well as the framing assumptions of the parties would facilitate explaining the policy output.

7.4.2. Objections of the MoA and the DoE to the Parliament's draft bill

On the other side, both the DoE and the MoA prepared some documents to analyse the Parliament's bill. In an extended analysis report on 26 January 2009, the MoA

[149] The draft did not specify which deputy.

highlighted the following issues, which, *inter alia*, indicate their assumptions towards the risk-generating system, as well as the policy prescriptions for dealing with the issue:

- "The scope of the law should be extended to cover field trials." This argument is in line with their view towards the risk-generating system and whether or not scientific research could be a source of risk.
- "It is not reasonable to have biotechnological experts in the NBC." This statement confirms again the view of the MoA that there should be a sharp separation of science from politics in a type of decisionist model.[150]

In a document comparing the Government's bill with the Parliament's bill, the DoE criticised several features of the latter. Chief among them in relation to the framing assumptions were: [151]

- Unfortunately, biotechnology is labelled as a technology that is definitely safe and provides undeniable benefits that exceed any risks. This notion is not true.
- A serious problem arises from overlooking the processes and activities of biotechnology including the intermediate products prior to release.
- It is not reasonable to have two biotechnological experts as developers of biotechnology on the NBC.
- The Parliament's bill is seriously inadequate because it does not require the applicant to provide scientific proof of safety.
- It overlooks the central monitoring and controlling dimensions of biosafety.

Nevertheless, the main Chamber made few changes in the sessions debating the new bill, in spite of the speeches and efforts of the head of the DoE to insert considerable changes in those sessions. Therefore, the final law of Iran was very close to the views of the MoH and the MoS, which was reflected in the new bill. In the next section, I shall describe the main Chamber process.

[150] This document was published on the Parliament's site. The numbers of the document are: subject code 250, serial number 9564.
[151] A document prepared by the office of the secretariat, although unpublished and without number. I have copied this document. Although I could not find the head of the DoE, I was able to connect with the head of the Iranian non-government environmental news network, who had a close relationship with the head of the DoE. He told me that in an interview he had had with the head of the DoE, she used this document to argue against the shortcomings of the Parliament's bill.

7.5. Enacting the law in the Chamber

Discussing the process and negotiations in the main Chamber may be worthwhile, given that the speeches of the head of the DoE as the representative of the Government[152] at the final stage of debating the draft law reveal how the head of the DoE was unhappy with the eventual contents of the biosafety law and tried to change it as far as possible. Initially, she recommended that the Parliament should reject the entire bill. By calling the new draft a proposal for developing biotechnology rather than one for protecting biodiversity and human health, the head of the DoE stressed the following points, some of them several times:

- "*Scientific documents should prove that biotechnological products are safe, especially with respect to the human health.*"[153] *"There is plenty of evidence suggesting that biotechnology could create allergies, gene transfer and so on."*[154] This is related to the previously mentioned framing assumption that influences the definition of the policy problem. Thus, for the DoE, biotechnology was still regarded as a thing that needed a proof of safety.
- *"There might be substantial problems arising from research activities, especially those conducting field trials. There should be adequate monitoring and control over these activities."*[155] Concern over research is a part of the assumptions about the risk system and the sources of risks, and whether research activities could pose considerable risks or not. Again, the DoE portrayed research activities as an important source of possible risks.
- "*How can some biotechnological experts, who are involving in biotechnology development, contribute to the National Biosafety Committee, a committee that should essentially monitor and control biotechnological activities? It is not possible to expect the producers to perform a controlling role as well.*"[156] So far,

[152] Although the Government was not unified, as I have explained throughout this dissertation, the head of the DoE represented the Government as the office of the secretariat, and therefore she mainly represented the concerns of the DoE as if they were the concerns of the Government.
[153] Second day of negotiations on 13 May 2009. Official Minutes of the Parliament. (Session 93 of the 8th Parliament)
[154] First day of negotiations on 12 May 2009. Official Minutes of the Parliament. (Session 92 of the 8th Parliament)
[155] Third day of negotiations on 17 May 2009. Official Minutes of the Parliament. (Session 94 of the 8th Parliament)
[156] This concern was restated in all three days of the negotiations on 12, 13 and 17 of May 2009. (Official minutes of the Parliament.)

the concerns of the DoE over the benefits and interests of experts not only led this department to identify research activities as an important source of risks, but also to propose excluding them from any activity related to implementing the law, especially their presence on the NBC.

- More generally, the head of the DoE complained about the Parliament's bill by stressing that "*the essence of biosafety is protecting biodiversity and the environment and human health, while the current draft does not meet this essential characteristic."*[157] It is now clear that this definition of biosafety was rooted in a specific view of the safety and harm of biotechnology, as well as a suspicious view of domestic experts working on developing biotechnology.

However, the DoE was successful only in inserting the following changes in the Chamber, while other parts remained unchanged in comparison to the new bill:

1- Moving the suggested location of the office of the secretariat of the NBC from the office of the President to the DoE
2- Removing the article stressing that refusing to authorise should only be based on proven scientific documents showing harm from the product
3- Cancelling an article indicating that the bodies that rejected the production or commercialisation of a product without proven scientific evidence could be prosecuted and might face considerable penalties.

However, one implication of the above changes was that the office of the secretariat for the NBC remained under the control of the DoE, which gave this department some power to contribute and possibly oppose the intentions of other Ministries to promote biotechnology.

7.6. The future: controversies or convergence?

The above narrative indicates that the biosafety law of the country was passed amid disagreements between the Ministries involved and the DoE. It was not only the DoE that was unhappy with the overall approach of the eventual law, and the MoA that was

[157] First day of negotiations on 12 May 2009. Official Minutes of the Parliament. (Session 92 of the 8th Parliament)

concerned about some parts of it, but the MoH and the MoS were also disappointed by the changes that took place in the main Chamber as the result of the efforts of the head of the DoE. The MoH and the MoS were especially unhappy with the shift of the location of the office back to the DoE, which in their view had essentially been the source of many problems in the past.

In a harsh criticism just after the second day of negotiations in the Chamber (13 May 2009), when the location of the office was shifted back to the DoE, the representative of the MoS called that decision "unfair" and even "illegitimate" because, in his view, the head of the DoE had misled MPs by presenting incorrect information. He also argued that the decision of the Parliament to omit the article which obliged organisations and Ministries to provide proven scientific information for banning biotechnological products was also unacceptable.[158]

In an interview on 20 May 2009, just three days after passing the law, the head of the office of the secretariat in the DoE argued that the final law suffered from shortcomings.[159] He referred to the issue of labelling, which, according to the law, is only necessary for imported and exported products, excluding those used for domestic consumption. He also criticised the scope of the law according to which even field trials were considered as a type of research and therefore free from any specific regulation. He mentioned that by locating the office in the DoE, the office would concentrate on its monitoring and controlling role, while there were still some problems with regard to the MoA as the National Focal Point, as that Ministry could not perform the proper controlling role because of its engagement in developmental activities. In his view, this required revising the law.[160]

After the end of the second session of the Chamber on 13 May 2009, and before starting the third and final session on 17 May, the head of the DoE in an interview on 15 May stressed that, according to the parts of the law that were currently approved by the main Chamber, the DoE would be able to not allow any type of genetic modification either on

[158] http://mehrnews.com/fa/NewsDetail.aspx?NewsID=877997
[159] http://www.farsnews.net/newstext.php?nn=8802301083
[160] According to the final law, the DoE was the office of the secretariat for the NBC and the MoA was the National Focal Point for international relations, especially with regard to the CPB.

animals or plants in its specific domains of responsibility, i.e. in wild nature and natural parks.[161] She added that the DoE would ask the MoA and the MoH to make sure of the safety of biotechnological products, which is related to their duties under the law.

The representative of the MoA on 7 June 2009, 20 days after passing the law, argued that although the biosafety law had positive aspects, it also suffered from some problems.[162] Among the main problems, he referred to the scope of the law according to which research activities, including field trials, were exempted from biosafety regulation. To resolve this problem, he proposed that the rules and regulations of the biosafety law, to be written very soon, could anticipate proper safety mechanisms for controlling field trials. However, the most important problem in his view was the shift of the office of the secretariat to the DoE, which might lead to substantial problems in the future. These interviews show that for the bodies involved, even passing the law could not be interpreted as a sign of their concerns having been met.

In short, these interviews published in the media reflect the points of disagreement and the issues which had been the main topics of conflict from the outset; the matters that were not resolved even by the passage of the law. However, the missing point in all these controversies is considering the assumptions that framed the views of the protagonists in this way, the assumptions that had never been a subject of discussion and remained unresolved.

While the law excluded research in order not to burden research activities, the office of the secretariat of the NBC is still in the DoE, which does not agree with the spirit of this law. As the office is responsible for coordinating several activities *vis-à-vis* biosafety, including the negotiations over finalising practical rules and instructions, it seems it has gained some power to advance its own view.

Signs of problems emerged a year after the passage of the law when a senior representative of the MoS accused the office of the secretariat of what he called "the wrong approach to biosafety" and being "in opposition to the provisions of the biosafety law". Referring to a

[161] http://mehrnews.com/fa/NewsDetail.aspx?&NewsID=878973
[162] http://www.farsnews.net/newstext.php?nn=8803170336

draft of rules and instructions for handling, transportation, import and export of GM products prepared by the DoE as the office of the secretariat, he argued that those instructions were absolutely unjustifiable because they presumed modified organisms were like untreatable diseases.[163]

In the next chapter, I will discuss the answers to the empirical and theoretical research questions posed in Chapter 3 as well as the possible contribution of this research to suggesting useful ways for addressing the policy problem of Iran, followed by a discussion of the broader theoretical and empirical implications and other possible contributions of this research in more detail.

[163] http://mehrnews.com/fa/NewsDetail.aspx?&NewsID=1084353

Chapter 8. Conclusion and Discussion

8.1. Introduction

This research has provided a detailed empirical study based on a theoretical framework that was built on two broad streams of literature. The topic of this chapter is to identify what are the implications of these findings. This question can be considered from different perspectives, such as:

1. What do these empirical findings suggest as the answers to the empirical research questions?
2. What does this research suggest as the answer to the theoretical question?
3. How might the answers to the research questions help in resolving the policy controversies in the case of biosafety regulation in Iran?
4. How might those findings help broaden or enrich current theoretical understandings?
5. How might the results of this research help in understanding the experiences of other similar countries, such as many developing countries that are members of the CPB?
6. Do the results suggest anything about the many different countries, such as industrialised countries?
7. Is there any implication for technology regulation and policy making in general?

I will discuss these questions in the remaining parts of this chapter.

8.2. Answers to the Empirical Research Questions

The main question of this research concerned the applicability of the concept of framing assumptions to explaining the controversies and changes in the case of biosafety regulation in Iran. I will restate the research questions posed in Chapter 3 and will discuss the answers to those questions.

- *What types of different frames or framing assumptions can be identified and elicited from the participatory organisations in the system of biosafety regulation in Iran?*

Summary answers to this question can be found in Table 7-1. A summarised version of this table, characterising the types of framing assumptions, is represented in Table 8-1. As the table suggests, several types of framing assumptions were elicited that largely affected the perceptions of the protagonists in defining the three main aspects of the policy, i.e. policy problems, the risk system and policy prescriptions.

Table 8- 1 Types of the identified framing assumptions

Definitions of the policy aspects	Framing assumptions
Understandings of the nature of the policy problems	• *Are technologies essentially beneficial or not?* • *Is biotechnology like other technologies or not?*
Comprehension of the risk system	• *Should the regulatory system trust the researchers and other bodies with promotional responsibilities? (Are they the best people to ensure the safety of their work, are they impartial, or is there a lack of facilities and equipment?)* • *Are the risks just physical (human health and the environment) or political?* • *What is the scope of physical risks?*
Policy prescriptions	• *Are biotechnological experts able to answer all the risk policy problems?* • *Are biotechnologists neutral or partisan?*

Regarding the policy problem, the empirical findings suggest that different assumptions about technologies, along with assumptions regarding the degree of difference between biotechnology and other technologies, largely affected the understandings and negotiating positions of the protagonists.

The risk-generating system as a part of the risk system is also understood differently by the antagonists according to their different framing assumptions. The degree to which the biosafety law could assume trustworthy researchers and organisations with promotional responsibilities is a distinguishing framing assumption. Scope of the risk in terms of whether or not it should include political dimensions as well as the scope of the physical risks and causalities within the system are two other pivotal types of framing assumptions.

Policy prescriptions were also different because of different framing assumptions regarding the sufficiency of biotechnology expertise to answer several risk policy problems, as well as different framing assumptions about the neutrality of biotechnology experts.

I am not claiming that these are all the framing assumptions in the system, but they are some different framing assumptions that I was able to identify by applying my framework, and I argue that to a considerable degree the differences between them could help explain the controversies in the system.

- To what extent are they different and even contradictory?

The answer to this question can also be found in Table 7-1, but I have reshaped that table in Table 8-2 in a way that reflects the differences. Table 8-2 does not include the detail of the framing assumptions as does Table 7-1, but instead the cells are coloured in a way that shows the contrasts between organisations and Ministries. As the table suggests, it would be possible to distinguish between three overall perspectives, the MoH and the MoS as extreme promotional approaches, the MoA as a perspective paying attention to both risks and benefits of biotechnology, and the DoE primarily concerned about the risks of biotechnology.

Regarding the safety or harm of biotechnology, the MoH and the MoS shared very similar assumptions as in their view, technology is generally safe, biotechnology is like other technologies and therefore biotechnology would not pose serious risks and should be considered safe, unless the opposite case was demonstrated. As a consequence, risk assessment studies should look for signs of harm rather than seeking to demonstrate that the technology is safe. On this basis, the policy problem for these two Ministries was not making the criteria for monitoring biotechnology development processes and products more stringent, but providing the means for exploiting the benefits of this technology as a type of technology development strategy.

The MoA had a different approach in that it appreciated the possible risks of biotechnology, assuming that risk is a general issue for all technologies. In this sense, a

GM product as an output of biotechnological research is similar to an aeroplane: using each requires considering their specific safety measures. Consequently, in the view of the MoA, the problem with biotechnology was just applying the routine procedures of risk assessment and risk management.

The view of the DoE with respect to the risks of biotechnology was conspicuously different from that of the other organisations, as this department adopted radically different framing assumptions. For the DoE, even other technologies could not be considered safe and beneficial, as for instance cars cause air pollution. Further, this department adopted another distinct assumption about biotechnology, perceiving it as essentially different from other technologies, and perhaps as a manipulation of nature that in turn might cause irreversible harm. Therefore, biotechnology could not be seen as safe at all, but as a problematic human activity, just some of which might not ultimately be hazardous. Thus, a main problem for the DoE was confronting and preventing the risks of biotechnology.

Table 8- 2 Summary of the overall findings of the research about the contrasts between framing assumptions in the biosafety regulation experience of Iran

Elements of framing	Contested issues	MoH	MoS	MoA	DoE
Assumptions affecting understandings of the nature of the policy Problem	*Presuming biotechnology safe or harmful?*	Framing assumptions			
		Safe	**Safe**	**Almost Safe**	**Harmful**
Assumptions regarding risk system	*Research activities as a source of possible risk?*	**No**	**No**	**Yes**	**Yes**
	Lack of the law as a source of political risk?	**No**	**No**	**Yes**	**No**
	Scope of the risk and the causalities within the system?	**Narrow physical approach**	**Narrow physical approach**	**Physical and political**	**Broad physical approach**
Assumptions regarding ways of dealing with the problem (models of risk assessment and risk management)	*Role of biotechnological experts in the process of regulation?*	**Scientists almost should regulate**	**Scientists should have a decisive role in all stages of regulation**	**Science and politics do the regulation**	**Only policy-makers should regulate**
	Separation of promotion from regulation?	**No**	**No**	**Partly**	**Yes**

The above sets of assumptions about biotechnology were in conflict with each other. There was a particularly sharp contrast between the assumptions of the MoH and the MoS on the one hand and the DoE on the other hand. The first group was seeking a law to be written on the assumption that biotechnology is essentially beneficial, while the DoE was trying to draft a law to avoid serious risks from biotechnology.

In terms of the risk-generating system as a part of the risk system, a contested issue was about the potential risks of research activities. In this regard, the MoS and the MoH shared a view that research would not impose any serious risks, mainly because the researchers are assumed to be the best placed people to ensure the safety of their work, and partly because of their former assumption that biotechnology itself would not impose serious risks. By actively rejecting any idea to consider research activities as a potential source of risk, those Ministries argued for a law to be drafted based on a high degree of trust of research activities.

For the MoA, research activities might be a source of potential risk not because of the partiality of the researchers as a burden of safety, but mainly because of the shortages of facilities in some locations in the country. Hence, the MoA supported the idea that research activities should be covered by the provisions of the biosafety law to ensure that they are being conducted under sufficient safety measures.

The DoE took a pessimistic view in this respect: for this department research should be covered by the law because researchers might choose not to meet the safety conditions due to their vested interests in developing biotechnology. In the view of this department, there was no basis for designing the law according to an assumption of trust in biotechnology researchers. On the contrary, the law should be drafted on a basis to include the activities of researchers and all other sources of potential risk, especially from the bodies that might benefit from biotechnology promotion.

There was another assumption about the risk system that distinguished the approach of the MoA from other Ministries and departments. The MoA frequently emphasised the necessity of having a law, arguing that the lack of a law would impose a type of political

risk for the country in its interactions with other countries concerning imports and exports; however, this Ministry sometimes compromised its opinions with the aim of approving the law as soon as possible. For instance, according to the data in previous chapters, this Ministry completely disagreed with locating the office of the secretariat in the DoE; however, it did not halt the processes of negotiation on this issue as the DoE had done in the two-day gathering.

Finally, the scope of the law was another aspect of the risk system and the perceived border of causalities within it that was perceived differently. For the MoH and the MoS, the scope of the law should be limited to the physical aspects of biotechnology, considering short-term, direct effects and effects on target organisms, mainly because assessing other types of impacts goes beyond reliable scientific judgments and therefore becomes invalid.

For the MoA, the scope of risk should also cover the political risks arising from the lack of the law. However, for the scope of physical risks, this Ministry suggested a case-by-case approach, meaning that the scope of assessing the risks should be individually determined in each case. This suggests that this Ministry did not reject the possibility of broader types of physical risks.

The view of the DoE about the scope of risk was more sceptical, as this department suggested considering a very broad scope for risks, covering long-term, indirect effects and also effects on non-target organisms.

Policy prescriptions or the ways of addressing problems were reflected in the proposals of the members about the proper mechanisms of risk assessment and risk management, and the responsibilities within this mechanism. However, antagonists adopted different views on how this mechanism should be established and how the responsibilities should be allocated and divided.

In this sense, the MoS and the MoH adhered to the idea that biotechnology regulation is essentially a scientific activity, while for the MoA it was a combination of science and politics, and for the DoE it was perceived as an entirely political and managerial job.

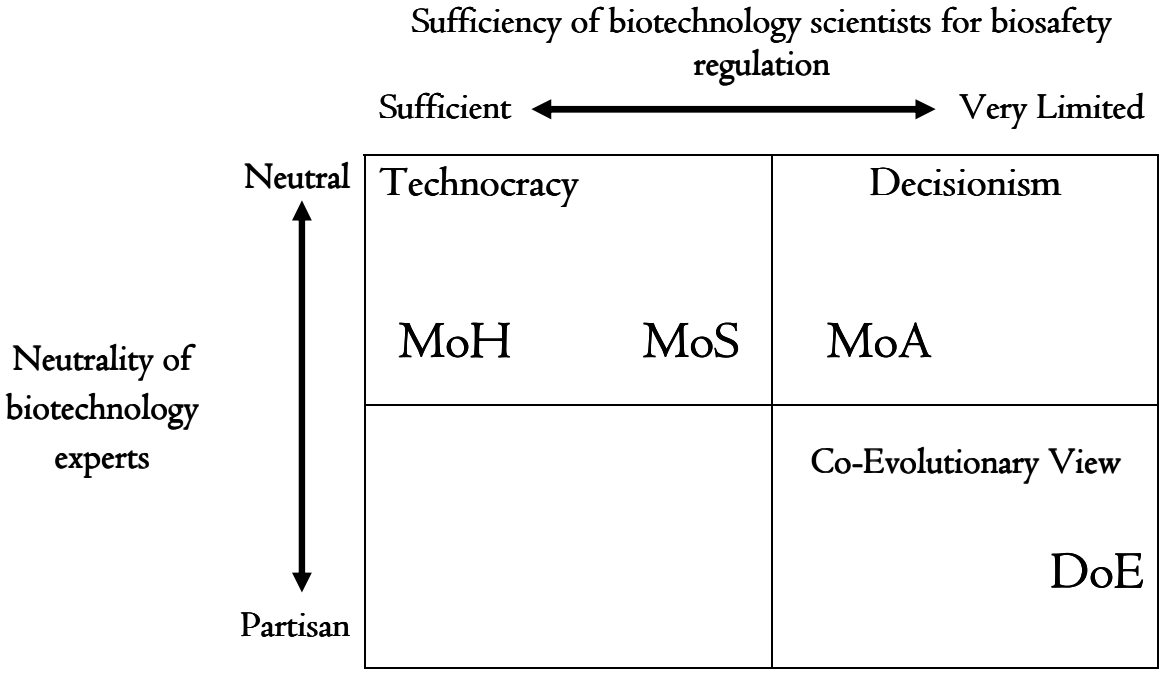
Therefore, while for the MoA there were some opportunities for separating science from politics, this idea remained meaningless for the other members as the MoS and the MoH considered science necessary at each stage, even in the NBC in cooperation with the policy authorities; the DoE, on the contrary, perceived no role for biotechnology scientists at any stage and it therefore assumed the separation of biotechnology scientists and organisations with promotional responsibilities from all regulatory activities.

By locating the assumptions of organisations such as in Figure 3-6 in Chapter 3 and modifying this to consider biotechnological scientists, it might be possible to characterise their prescriptions as is shown in Figure 8-1. However, as Figure 8-1 denotes, these are not general assumptions about the neutrality or sufficiency of science, but assumptions about biotechnological experts in the context of biosafety policy making in Iran. The horizontal line represents the sufficiency of biotechnological experts to answer the questions of biosafety regulation while the vertical line represents the extent to which those experts are supposed to be neutral in their judgements.

As Figure 8-1 shows, the MoH approached the legislation based on a view very close to the technocratic view, presuming that biotechnology expertise would be sufficient for biosafety policy making (excepting the NBC that essentially should have policy-makers in its compositions) while conceiving biotechnology experts as a type of unbiased group. For the MoS, although biotechnology scientists might not be sufficient for the purpose of deciding biosafety regulations, they should have a decisive role in all stages and at all levels of decision making to make sure that a scientific approach is present in all decisions. The view of the MoA was very close to the decisionist approach in which, although the biotechnology experts were considered neutral, their expertise was not seen as sufficient to respond to all aspects of biosafety policy making, and the task of goal setting should be allocated to politicians rather than scientists. The view of the DoE is one that believed the bodies with promotional responsibilities should not be given any decisive role, instead merely advising policy makers for specific purposes, as they might be driven by their organisational and individual interests. I characterised the view of this department as a co-evolutionary view; however it is not the one suggested by Millstone (2009), which also considered the framing assumptions and the reciprocal links between science and policy,

but is co-evolutionary in a sense that accepted scientific experts could be partisan and should therefore not have decisive roles, only advisory roles.

Figure 8-1 Assumptions about the sufficiency and neutrality of biotechnology scientists in the process of regulation



Overall, the findings of this research suggest that the framing assumptions of the organisations and Ministries were different and could provide an explanatory account for the long-lasting controversies, especially considering the fact that the members did not discuss these assumptions in the three stages of negotiation.

- *How did those framing assumptions change over time and why?*

Comparing Tables 5-1, 6-1 and 7-1 for the three rounds of negotiations reveals that there was no significant change in the framing assumptions of the protagonists, which in turn confirms the idea that the framing assumptions had a persistent characteristic over time and did not change, mainly because those assumptions were rarely explicitly addressed during the negotiations.

- *Can the changes in the framing assumptions help explain changes in the policy outputs of each stage?*

As the framing assumptions did not change, there could be no links between the changes to the policy output and the changes of the framing assumptions. In other words, the persistent character of the framing assumptions could provide an explanation for the long-standing controversies, but could not explain the changes in the policy outputs of the three processes of negotiation.

- *If the framing assumptions remained unchanged, is it possible to understand the changes in the output of each policy stage in the light of changes to the dominant power?*

The empirical investigation has shown that the policy outputs of each stage can be closely linked to the power relations and the dominant power structure, and on this basis, the policy changes could be explained in the light of the changing of the dominant power at each stage. In this sense, the results of this research endorse the approach of Murphy and Levidow (2006) in combining the notions of power and framing to argue that the policy output would reflect the frame of the dominant power and a change of the dominant power would therefore change the policy output.

However, the difference between the case of Iran and the experience of the EU is in the way power relations changes, at least for the transition from the first (CC) to the second stage (RC) of negotiations. For the EU, the dominant power could not resist public disputes and criticisms that questioned the legitimacy of their frames (Murphy and Levidow 2006). In the case of Iran, the dominant power changed through leveraging the organisational authorities, as happened in the transition from the first to the second round of negotiations, when the DoE used its authority as the office of the secretariat.

However, the final parliamentary stage of negotiations was different in terms of how framings and power played role in the policy output. Although the transition from the RC to the agricultural committee of the parliament was associated with the change of decision-making power from the DoE to MPs, the members of the parliamentary

agricultural committee were not familiar with the issue and therefore they did not initially impose a specific set of framing assumptions. Instead, the process was for them to listen to the arguments of the antagonists in the agricultural committee sessions and decide about the eventual content of the Biosafety draft to be presented to the main Chamber for final decision.

In this sense, the contending ministries found a new opportunity to present their views about the Biosafety law and they tried to convince the members of the agricultural committee that the underlying approach of the government's bill (as a result of RC sessions heavily influenced by the DoE) was not on the right track; in particular by emphasizing that it was not supported by the chief biotechnological organizations in the MoH and the MoS. In this way, they partly used their scientific reputations as a means to convince the MPs that those ministries better understand the issues and so could formulate more appropriate policies.

In addition, those ministries also used their framing assumptions, such as emphasizing the importance of biotechnology for economic progress and welfare, as another tool to convince the MPs that their approach would better suit the conditions of the country; thus they gained greater power in the final stages of the negotiations. While some sorts of framing assumptions were about who would better take the responsibility of implementing the law, those ministries were also successful to diminish the power of the DoE by emphasizing their framing assumption on the necessity of upholding expertise in implementing the law that in turn led to change of the office of the secretariat.[164]

The first stage of negotiations could not yield any draft policy because different organisations were on a par in terms of their decision-making powers and their contradictory views prevented them reaching an agreed conclusion. The second round of negotiations ended with a draft very close to the views of the DoE, as the head of this department largely leveraged its organisational authority to affect decisions in line with its own approach. Finally, the output of the Parliamentary process was a draft very close to the views of the MoS and the MoH, mainly because they could gain a more influential

[164] However, in this case, the head of the DoE could turn it back to the DoE in the main Chamber.

position compared to the DoE by convincing MPs that only their approach was scientifically sound and by using different tools including their framing assumptions.

However, while the differences of power can contribute to explaining the change in the policy outputs, merely understanding the power relations alone could not help in identifying or predicting the output. This means that knowing which organisation was dominant would not alone be helpful in knowing what the policy output would be, but by knowing the dominant power as well as the framing assumptions of each institution, it would become possible to predict what the policy output would be.

In summary, the research has concluded that the differences between the framing assumptions of the protagonists within the system persisted in a way that caused each of them to adopt a different approach, which then could not coherently come together in a draft biosafety law. In addition, as those framing assumptions did not change over the three rounds of negotiations, the changes in the power relations, which occurred partly because of the utilisation of those framing assumptions to gain influence in the last stage of negotiations, can account for the changes in the policy output. The policy output itself could be understood and perhaps predicted by knowing both the framing assumptions as well as the power relations.

8.3. Theoretical Contributions

A theoretical goal and aspiration of this research was concerned with making a link between two broad and separately developed streams of literature (public policy analysis and technological risk regulation) in order to develop a theoretical framework applicable for analysing the case of Iran. In this part, I will discuss the theoretical insights that could be inferred from this research, in terms of the unit of analysis it adopted and with respect to its theoretical framework as well as other possible contributions.

8.3.1. Framing Assumptions and Narratives

A prime concern in developing a framework for this research was the difference between two units of analysis applied in the literature. The public policy analysis approach tends to use the notion of narratives, as a type of generic stories, to analyse the controversies

between Governmental agencies or interests groups within a country, while the literature on risk regulation applies both notions of framing assumptions and narratives as sources of disparities among countries.

As a result of the present research, it seems that applying the concept of framing assumptions can provide more explanatory power than the concept of narratives. For instance, considering the definitions of the policy problem, the general view regarding whether or not technologies could be seen as useful or as a source of risk is a type of generic narrative that not only implies what the problem is (i.e. technology itself), but also what the solution might be (i.e. constraining or monitoring the process of technological development). However, the narrative alone cannot provide as rich an explanation of controversies as the concept of framing assumptions, for two reasons.

Firstly, the differences between organisations' and Ministries' views were not based on the general narratives they had, i.e. technology development is risky, therefore we should restrict or control it, but about the prime assumptions of these narratives, i.e. whether or not technology development is risky in this context. In this sense, organisations and Ministries held different assumptions but not different narratives. Secondly, this narrative could not capture another important assumption, i.e. the extent to which biotechnology is seen as being like other technologies. Therefore, even if organisations and Ministries had adopted similar narratives about the risks of technology development, differences in this assumption could lead to substantially different approaches to GM safety regulation.

Nevertheless, there are also many other framing assumptions, like the assumptions of organisations towards each other, which might not be captured by the notion of narratives, which in turn would undermine the explanatory power of the research. Generally, narratives are broad stories that might underlie some differences, but they may not capture many relevant ideas and assumptions, especially because a variety of assumptions would be involved in each case (i.e. context-specific assumptions), which might not be articulated in the general narratives.

Thus, the current research borrowed the notion of framing assumption from the works on analysing biotechnology regulation and experiences of risk assessment and risk

management at the level of country cases to examine the policy controversies at the level of organisations, which had previously been analysed mainly in the literature of public policy using the concept of narratives.

8.3.2. Relations between the assumptions

The above findings also suggest that the framing assumptions are interrelated and could affect the distinguishing characteristics of protagonists regarding different aspects of the policy, i.e. policy problems, risk system and prescriptions. For instance, the negative assumption of the DoE about the neutrality of experts not only led that organisation to consider the process of research as a source of risk, but also to propose leaving the experts out of several stages of policy implementation. As another example, the importance of political factors in defining the risks of biotechnology affected the view of the MoA in a way to both consider the political risks and the importance of compromising for the sake of the law, as well as conceiving a very important role for political authorities in the decision making process.

8.3.3. Contributing to Public Policy Analysis

These findings might also have theoretical implications for the literature on public policy analysis. In the context of public policy analysis, and the primary approach known as the idea-based view, which for discussing controversies has mainly used the notion of narratives, it seems that the concept of framing assumptions might provide a greater explanatory power in comparison to only applying the concept of narratives. In other words, while narratives are necessary to capture different features and controversial issues within cases, it might be possible to deepen the analysis by considering the framing assumptions underlying those narratives.

However, there is another important aspect of the literature of public policy analysis. In Chapter 3 and the discussion over the approaches to public policy, I argued that there are two main views on explaining the controversies: firstly, the instrumental rationality version of rational-choice theory, suggesting that the institutional actions are the function of their objective interests, and secondly, emphasising framing assumptions that also

reflect the interests of protagonists. The findings of this study regarding framing assumptions might help more in investigating the relations between the interests of organisations and their framing assumptions.

As far as considering the DoE and the MoS, interest-based theories might suggest that the objective interests of those organisations were the main factor causing controversies, as the DoE is an organisation that is supposed to protect the environment and it therefore could be expected to oppose biotechnology development, while the MoS is a Ministry responsible for developing science and technology through research, and therefore could be expected to be concerned with promoting biotechnology science rather than protecting the environment.

The rational-choice or interest-based approach could not, however, provide a satisfactory account of the approach of the MoH and the MoA. This is because the former is primarily responsible for human health in the country, not science and technology development, and therefore could be expected to be concerned with potential risks of biotechnology for human health. However, as the findings of this research suggest, the Iranian MoH had no concerns about biotechnology development. On the contrary, the MoA is the body responsible for ensuring that there is enough food in the market for the population. In this sense, the interests of this organisation could be expected to support the promotion of GM crops which in turn could lead to increased productivity. However, I found in this research that this Ministry did not conform to those expectations.

In this way, the view proposing that framing assumptions are important in shaping the understandings of protagonists of their interests could provide a more satisfactory explanation than the one referring only to interests. The approach of the MoH could be better understood in the light of considering its framing assumptions about biotechnology as a technology similar to other technologies without imposing substantial risks for human health or the environment. Based on that assumption, this Ministry strongly rejected any criticism of biotechnology and defined the policy problem as facilitating biotechnology development. To the MoH, scientists, and in this case biotechnological

experts, are best qualified to decide about the safety of biotechnology, without any intervention from political authorities.

The view of the MoA could also be understood in the light of its framing assumptions. To this Ministry, the risks of biotechnology were not just physical risks, but also political risks arising from the international commitments of Iran that could impinge on international transactions such as imports and exports. Therefore, this Ministry refused to accept the political risks of cultivating Iranian GM rice without first having a biosafety law. The MoA believed that scientific judgments are neutral; however, it was concerned about a lack of sufficient knowledge and facilities in Iran's GM laboratories and research centres that might affect the process of research and lead to imposing further risks on domestic agriculture.

Moreover, the interest-based approach could not provide an account for why the DoE rejected any idea for incorporating biotechnological experts into the implementation of the biosafety law, while the framing assumptions approach could also help explain the perspectives of the DoE in this respect by pointing to the negative assumption of the DoE towards the benefits of bodies with promotional responsibilities.

In short, while the interest-based approach assumes that objective interests can conflict, it cannot capture the hidden assumptions that largely influence the understandings of actors and their consequent interests. If an organisational interest is protecting the environment, presuming something to be harmful will lead that organisation to prevent that harm, while presuming something to be safe could lead it to ignore potential harm.

8.3.4. Framing Assumptions and Power

The relationship between policy change and policy controversies is another topic about which this research might provide new insights. As the controversies have been analysed and explained in the light of the persistent framing assumptions of the protagonists, the question of why there were so many changes in the policy can be better understood by considering the power relations and the dominant power that was able to impose its own view. Nonetheless, framing assumptions could also be used as a means to gain power.

When there was no dominant power, there could be no agreement and no policy output. Moreover, knowing the framing assumptions of the protagonists and the power relations might enable the researcher to predict the policy output, which would likely reflect the views of the dominant power.

8.4. Contributing to resolving policy controversies

In the introduction of this thesis, I stated that a main practical problem in the system of biosafety regulation in Iran is the long-standing controversy within the system and among the protagonists involved in the process of drafting the biosafety law and, later, implementing it. The theoretical approaches applied to the research suggested that the differences and contradictions between the framing assumptions of the organisations could explain why those controversies remained unresolved for so long. Thereby, the question is how could the findings about the framing assumptions contribute to suggesting useful ways of resolving the problem.

Resolving the problem conveys two different senses. On one hand, it might refer to the issue of truth and the ways of finding and identifying the correct assumptions in comparison to the false assumptions. However, as I have discussed throughout this research, framing assumptions are a kind of general worldviews containing many normative aspects that cannot easily be checked against a reality 'out there'. On the other hand, the resolution of the problem could refer to the pragmatic resolution of the policy controversies. The following discussion presupposes the second understanding of resolution.

At first glance, the solution might look simple: as the framing assumptions are different, the changing of those assumptions could therefore be a solution. However, the point is that it is hard to estimate how framing assumptions would change considering that they were not a subject of discussion during the process of negotiation. A closer view of the topics of discussion in the sessions reveals that the main topics of discussion were not those different framing assumptions, but reading a previously-written draft of a biosafety law (at least for the two stages of the CC and the RC). The chair of the sessions of the CC, who was the head of the office of the secretariat located in the DoE, deliberately did

not allow the members to discuss their framing assumptions deeply, and the head of the DoE as the chair of the RC sessions used her authority to end various discussions and finalise the draft as soon as possible.

As the empirical chapters have shown, the protagonists in the system used different strategies to try to exercise power and overcome opposing views. While the head of the DoE leveraged her political authority to influence the decisions in the sessions of the RC, the MoS and the MoH used their scientific reputation to discredit the DoE as a non-expert organisation and almost entirely irrelevant to biosafety and biotechnology regulation, a tactic that eventually worked in the Parliamentary discussions to convince MPs that the view of those Ministries (i.e. the MoH and the MoS) were scientifically sound, disparaging other views as non-scientific and unsound.

One conclusion could be that the topics of many discussions were not the framing assumptions, but efforts concentrated to gain power and make particular opinions dominant. Putting this understanding beside another fact that protagonists did not explicitly acknowledge that a barrier to progress and resolution of the conflicts was the persistence of their divergent framing assumptions, the following suggestions could be made for helping the policy making experience and possibly resolving such controversies:

1. If the protagonists are informed about the role and the importance of framing assumptions in shaping their views and the resulting controversies; and
2. If the protagonists are asked to reflect on their own assumptions; and
3. If the protagonists are informed about the variety of other framing assumptions that were held by other Ministries and organisations and the differences between those assumptions held by other organisations and their own assumptions; and
4. If different types of sessions are organised specifically to discuss the framing assumptions without any specific concerns about a proper biosafety law;

Then the controversies might be resolved, or it might lead to a partial resolution by achieving agreement on some assumptions but not on others; it may lead to no agreement at all, or it might even exacerbate the conflicts. These four steps are in line with the suggestions of the Schon and Rein (1994) as they argue that the process of frame

reflection might lead to resolving policy controversies. Nevertheless, whatever the result of such a dialogue, a benefit would be making the framing assumptions explicit in a way that every organisation would know that its perspective and approach was based on specific types of framing assumptions.

In more practical terms, those steps could still be followed as protagonists are continuing to discuss the practical rules and procedures of risk assessments and risk management in order to implement the law. There may be an opportunity to ask them in their sessions to pause their discussions about those practical rules and reflect rather on their framing assumptions and the framing assumptions of others, and how those assumptions had influenced their approaches to setting those practical rules. If they could reach some agreements concerning their framing assumptions, then this pause might not only lead to clearer and more explicit rules and procedures, but also it might encourage them to revise the law and prepare a new Biosafety bill to replace the previous one with another based on more harmonized framing assumptions.

As a further practical step, there might be other opportunities to raise these issues, such as raising them at the annual biotechnology congress, at which different protagonists involved in biotechnology, including those participated in the Biosafety regulation process, could take part. Those initiatives in turn might lead to taking new steps in changing the Biosafety law.

By reflecting on framing assumptions and making them more explicit, if protagonists could not reach an agreement, a further step could be discussing the criteria that might help in choosing between those assumptions, i.e. if a resolution could not be achieved. On this basis, the protagonists could discuss the variety of criteria according to which they need to choose between the framing assumptions.

If this step failed, then it would be possible to apply political authority and power as the final resolution to impose a dominant frame. In one way, this is like the second and third stages of negotiations in which the dominant power imposed its view, but with a sharp difference. While in the process of negotiations protagonists exercised power without acknowledging the diversity of framing assumptions, in this formulation the highest

political body in charge of decision making should consider those assumptions and make a choice between them.[165] Therefore, the question would not be one of policy design, but a choice between current and explicit framing assumptions as the foundations of the biosafety law.

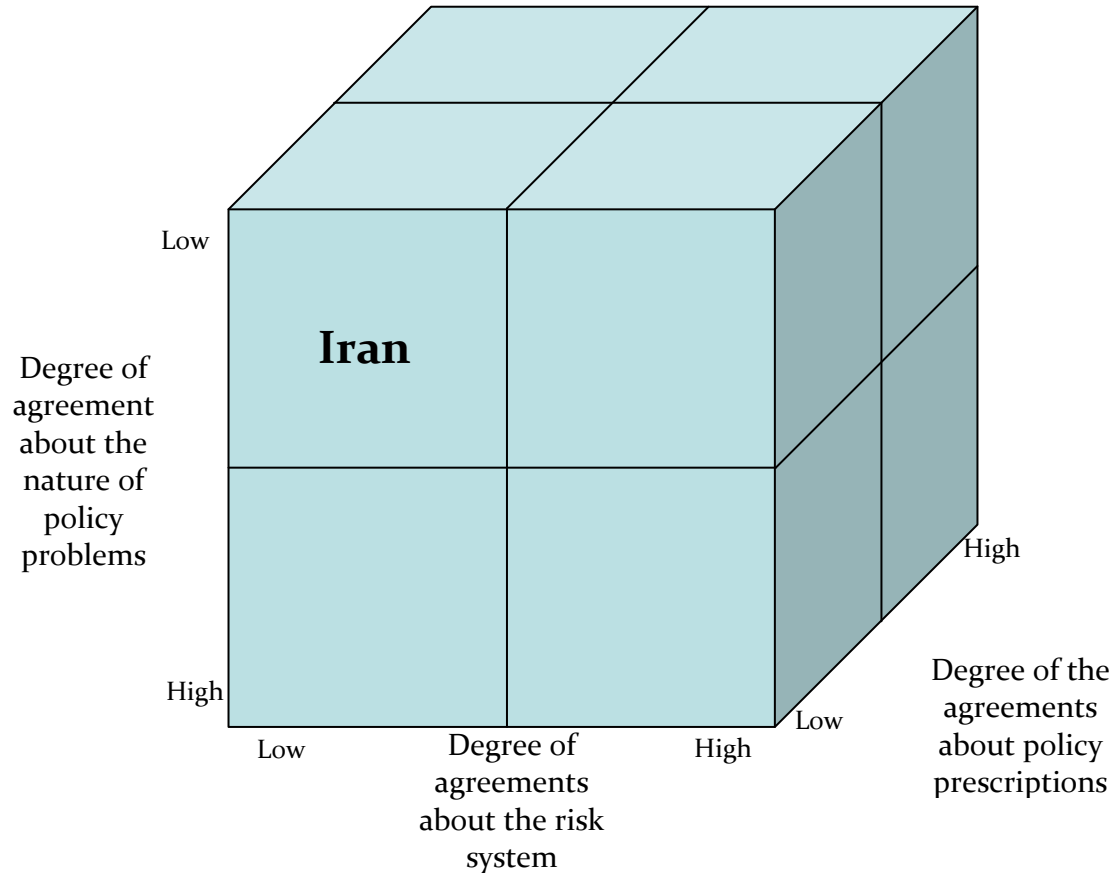
8.5. Applicability of the Framework to Similar Countries

Another contribution of this research might include the application of its developed framework categorising different types of framing assumptions. This framework was developed by synthesising two broad and different literature streams: on one hand the literature of public policy analysis with specific attention to the policy controversies to consider the policy narratives and discourses as a prime source of conflicts and on the other hand, the literature of technological risk regulation deploying the concept of framing assumptions to analyse differences and controversies, which is largely less concerned about disputes within countries.

The framework I used for this research was based on a general classification of the aspects involved in the Iranian experience of policy making (i.e. policy problems, risk system and prescriptions) that might be perceived differently because of the different framing assumptions protagonists adopted. On this basis, it might be possible to develop a cube including three axes, each of which characterises one aspect of my framework. Figure 8-2 represents this model.

[165] For instance, that higher authority could be the Supreme Leader.

Figure 8- 2 Characterising the extent and dimensions of controversies



On this basis, there might be disagreements about the policy problem, about the risk system including the causes of the problem and the scope of risks, and the policy prescriptions. The case of controversies within Iran was a case of controversies and disagreements in all of these three dimensions because of several contrasting framing assumptions of the organisations involved in the process of regulation.

Similar to the case of biosafety regulation in Iran, there are many other countries which are dealing with setting their biosafety laws because of their commitments to the CPB, and are struggling to develop such a law. A prime issue for them, similar to Iran, might be a lack of agreement about policy problems, the risk system and the prescriptions for addressing those problems. Hence, it seems that the general framework of this research for eliciting framing assumptions could be useful for analysing the cases of those countries that have witnessed a similar level of controversy in the way of passing their biosafety law.

For instance, as Gupta and Falkner (2006, 2009) discuss in the context of Mexico, in the early days of starting the negotiations in 2003, the Department of Environment in that country succeeded in demonstrating the importance of the CPB. However, opposition of different groups emphasising a desire to join the free trade agreements (like NAFTA) was finally able to overcome the restrictive views of the Department of Environment and eventually two chief experts in the Academy of Science drafted a new version of the biosafety law emphasising both the risks and benefits of biotechnology. Although the information about the case of Mexico is limited, it seems that the evolution of that country's controversies around the biosafety law were similar to those in Iran, consisting of controversies about policy problems, the risk system and the prescriptions.

While the controversies over the biosafety law in other countries might be very similar to the case of Iran, policy changes do not necessarily only take place because of changes in power relations, as in the case of Iran. In fact, policy changes need to be analysed with a detailed consideration of the structures and the involved actors in those countries such as the public, the media, the private sector, international agencies and so on, assuming that the framing assumptions are persistent for a long period of time. However, it is always possible that policy changes come from changes in the framing assumptions.

8.6. Discussing Implications for industrialised countries

The model presented in Figure 8-2 might also be able to characterise policy controversies in the cases of the USA and Europe as is shown in Figure 8-3. For instance, the experience of the USA in regulating biotechnology risk was an experience in which there were no disagreements about the risk-generating system, presuming products to be a source of risk and a limited physical scope for that perceived risk. Moreover, there were few contentions over the policy problem, as protagonists adopted biotechnology risk as the major problem to be addressed. Finally, there were limited disputes about the policy prescriptions and the roles and responsibilities of organisations. Therefore, the controversies were mainly confined to some scientific disagreements about the proper ways of calculating risks.

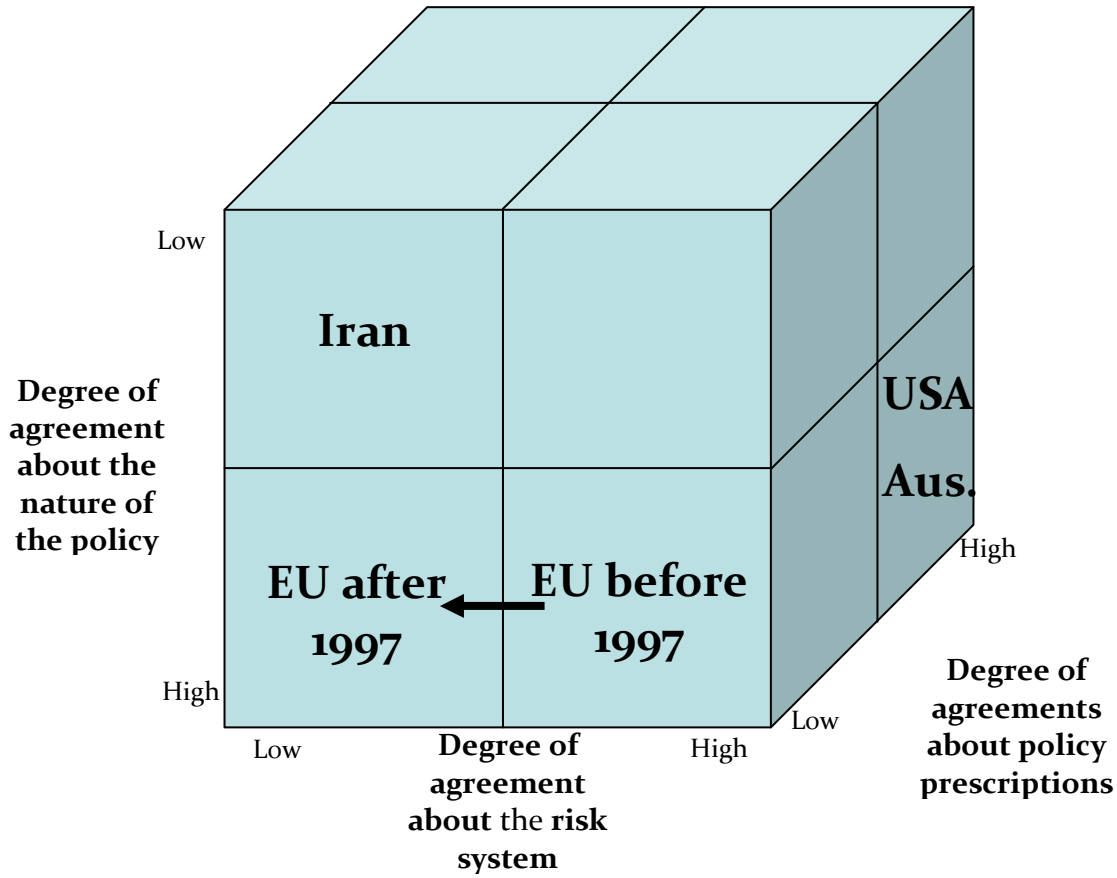
Conversely, although the EU generally accepted the policy problem as the risk of biotechnology, there were several disagreements about the risk system especially after 1997 either in terms of the risk-generating system or the scope of the risks. While public and the media insisted on a system including both products and processes as a source of risk-generation and a wider scope for assessing those risks, large GM companies suggested a narrower system either in terms of the sources of risk-generation or in terms of the scopes of those risks. There were also some disagreements about the roles and responsibilities, not between organisations, but about the proper role of the EU authorities and member states' organisations.

Directive 90/220 on the contained use of GMOs was the beginning of the European effort to build a harmonised territory in terms of biotechnology regulation by considering the importance of fighting the adverse effects of biotechnology. This Directive was replaced around a decade later by Directive 2001/18, as result of public debates, on the deliberate release into the environment of GMOs that broadened the scope of assessment of possible risks to cover long-term and indirect effects as well as the effects on non-target organisms. A complementary EC regulation in 2003 on GM food and feed provided the pre-marketing authorisation of GMOs.[166] Both aimed to set science-based standards for human and animal health and environmental risk assessment, while Regulation 1830/2003 also provided rules on the traceability and labelling of GMOs and the traceability of GMO-derived food and feed.

Therefore, this framework could also be used for tracing the dynamics of disagreements. In this sense, the controversies in the EU before 1997 were largely not about the risk system. But the involvement of the public and the media led to raising new controversies about the risk-generating system as well as the scope of those risks. In this sense, while the EU was experiencing disagreements about the policy prescriptions for addressing risks, it moved on to higher-level disagreements arising from public debates on the risk-generating system as well as the scope of risks, as two parts of the risk system.

[166] EC regulation number 1830/2003

Figure 8- 3 Characterising disagreements within other territories



Nonetheless, this framework represents a heuristic tool for characterising the types and degree of controversies without any detailed characterisation of the possible framing assumptions underlying the policy perspectives and positions. In this sense, it would be possible to characterise Austria as a country without considerable disagreements in terms of the risk system, policy problems or policy prescriptions in a similar cell to the USA. However, the approach of Austria to emphasising the desirability of organic foods, and their use of a benchmark of appraisal, combined with rejecting GM products, is radically different from that of the USA, although they are both located in a same cell of this particular matrix.

Finally, the diversity of framing assumptions within the EU might jeopardise the idea of having a converging regulatory system as far as it would be difficult to exercise centralised power to force member states to adopt certain framing assumptions. For instance, the recent communication of the European Commission to the European Parliament

discussed that the case of some countries that had prohibited or restricted cultivation on their territories where the EU scientific assessments had concluded that those measures were not justified. On this basis, the communication report proposed a new system under which the member states have the freedom to decide on the cultivation of GMOs in their territories (EC COM 2010).

8.7. Extending the application of the concept of framing assumptions

I began my theoretical discussions by discussing the models of risk regulation and the differences between the four models of regulation. I argued that the co-evolutionary model of regulation could provide a better explanation of the controversies than three other models (i.e. technocracy, decisionism and inverted decisionism) because it highlights the effects of socio-political factors that could provide some prior framing assumptions to the scientific risk assessments. However, as the case of Iran was not contentious regarding experiences of risk assessment, but with regard to a general level of identifying the goals of biosafety and the means of implementing those goals, I have referred to the literature of public policy which could develop a theoretical framework suitable for the case of Iran.

This research was based on a case different from cases of risk assessment, and has shown that it might be possible to apply the concept of framing assumption to issues wider than just framing of risk assessment. In this sense, framing assumptions could be used to analyse controversies in the process of legislation. It might also be possible to extend the application of framing assumptions to issues other than risk, for instance to cover framing assumptions concerning benefits. In addition, as I have applied the notion of framing assumptions at an organisational level, it might be possible to apply the concept to other levels of analysis (e.g. individuals, groups or firms).

8.8. Proposals for further research

There could be several suggestions for further research following the results of the current study. Firstly, it would be possible to define a type of action research to test how much a process of a few mediated sessions of negotiations explicitly to discuss the framing assumptions between organisations might help in resolving controversies. For this

purpose, the researcher could implement the suggested steps in section 8.4. It would be interesting to see how protagonists might reflect on their own framing assumptions and the framing assumptions of each other, and how they might react to those conflicting assumptions in a session that was directly designed for this purpose. The results of holding such sessions might provide further insights for inquiries into the resolution of framing conflicts.

Secondly, as the developed framework might be used for wider areas of decision making and in various contexts, it may be possible to define a similar research programme in other countries experiencing a high degree of controversy in their biosafety regulation. For instance, as Karembu et al (2010) described the process of biosafety policy making in Kenya, deploying fewer theoretical tools to analyse the controversies, they pointed out that policy controversies were alive throughout the process, although a group emphasising a precautionary approach could not seize power in any stage of the decision making. Keeley (2006) reported a similar level of controversy in China where legislation has been taking place behind closed doors with minimal outside access to the minutes of the debates, let alone voice recordings.

Further, it might be possible to examine the applicability of the framework and approach of this research to other cases of controversial regulation, either in Iran or in other countries. Policy making is a controversial activity and disputes could happen in several cases of policy making other than just risk regulation. In this vein, it might even be possible to apply the framework of this study to the cases that have previously been analysed in the literature, using the concepts of narratives or discourses (such as the three cases discussed by Shon and Rein 1994). The question would then be whether or not considering framing assumptions could provide a better explanation in comparison to the explanation suggested by Shon and Rein (1994).

Another possibility would be examining the degree to which the concept of framing assumptions could be extended to analyse the assumptions underlying different views on benefits. For instance, a question might be: do the persons discussing the risks and benefits of biotechnology, or even other technologies, consider the same scope of risks

and benefits, or do they consider a wider scope for risks (i.e. long-term, indirect effects and effects on non-target organisms) while suggesting a narrower scope for benefits? Further, the issue of comparing risks and benefits also could be considered as another topic of investigation because if arguments about risks and benefits depend on different sets of framing assumptions, then the question would be: how might it be possible to suggest a way to balance the framing assumptions and then compare risks and benefits?

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